# Global Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices

**Prepared by**

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# Preface

### *Purpose*

This is the fourth edition of a report first issued in May 1999. This report seeks to collect and compile information on the regulations relating to the importation of pre-owned (used and refurbished) capital medical equipment in countries around the world. It also includes some information on market demand for such equipment.

Although this report is intended to serve as a general reference, it is not a definitive study and data is not available or is incomplete for many countries. This report is formally updated annually, but revisions to the country entries are made throughout the year if new material becomes available.

This report does not attempt to address the issue of re-use of single-use devices. Such re-use remains a controversial practice and poses different safety issues than pre-owned capital equipment. Moreover, single-use devices are typically reprocessed by or for the original purchaser and thus generally do not enter into international trade.

### *Sources*

The main source for this report is responses filed by the staff of the U.S. Commercial Service (CS) stationed in U.S. embassies around the world to an annual request for information. This request, made by the Office of Microelectronics, Medical Equipment, and Instrumentation (OMMI), asks the Commercial Service trade specialists to review the existing entry and provide answers to the following questions:

1. Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?
2. Can public health institutions buy used or refurbished medical devices?
3. Is there a market for used or refurbished devices?
4. If there is a market, what types of used or refurbished medical equipment are in the greatest demand?

The responses provided by the trade specialists vary from full-length reports—typically *International Market Insight* (IMI) or *Industry Sector Analysis* (ISA) reports—to short replies submitted by cable or e-mail. In many cases, the specialists simply confirm the existing entry. Entries submitted in report format are given the title and date of the report. Other entries are simplified identified by whether they were submitted to OMMI by cable or e-mail and the date it was submitted. If the trade specialist confirms information submitted in previous years, both the original date of submission and the date of the confirmation are provided.

Over 50 USFCS posts responded to the cable in 2002 (44 responded in 2001). These posts either prepared new IMI reports on pre-owned-medical equipment or sent a cable or e-mail to OMMI addressing the above questions. All entries in this report identified as being a report submitted by a CS post via e-mail or cable and bearing a date in 2000, 2001, or 2002 represent responses to OMMI's request.

The report also includes a small number of reports on the medical-device sector prepared by the CS trade specialists independently of OMMI's request for information on the used-equipment sector, as well as some cables that the CS posts submitted in 1998 in response to a request from the Department of Commerce soliciting information regarding import regulation for used and

refurbished equipment generally. Entries based on responses to this request carry a source indicating that they were submitted by the CS post via cable and bear a date in 1998.

Although an effort has been made to preserve the text of the original sources as much as possible, text has been reformatted and abridged in order to present a standardized and concise format. In some cases, the original sources have been summarized or edited.

### *Limitations of This Study*

Because of the limitations of the sources, this report can not be considered a definitive study of import regulations relating to pre-owned medical devices. Information, unfortunately, remains lacking for numerous countries.

In addition, many of the cables that were in response to the 1998 request for information about import regulations for used/refurbished equipment do not explicitly deal with medical equipment. The reporting officer, for example, may have looked only at general import regulations and thus not considered the possibility of more restrictive health regulations that affect the importation of used medical devices.

Finally, medical regulations are constantly changing. What may have been accurate when the market research was prepared may not be the case today. In addition, custom or health officials may interpret regulations that do not seem to present a problem in such a way as to result in market restrictions.

### *Updates of This Report*

The most recent version of this report will be posted to ITA's Medical Equipment home page, www.ita.doc.gov/td/mdequip.

Users of this report are encouraged to inform OMMI of any information found to be out of date or inaccurate. Contact:

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# Executive Summary

### *Findings*

Information on import regulations for pre-owned medical devices was available for 99 markets.[1]

Of these 99 markets, 78 markets appear to permit the unrestricted importation of used or refurbished medical equipment on the same terms as new.[2] Sixteen markets impose restrictions. Five generally prohibit the importation of pre-owned devices.

For the purposes of this report, unrestricted importation of used or refurbished medical equipment on the same terms as new means that *if a device has been approved for sale in a market,*

- That the device can be imported either as new or pre-owned condition;
- That the pre-owned device is not subject to additional safety or registration requirements; and
- That the pre-owned device is not subject to duties and tariffs not also levied on like new items.

Such unrestricted importation roughly corresponds to the unregulated resale of medical devices in the internal U.S. market—the U.S. Food and Drug Administration does not regulate the resale of medical devices.

Unrestricted importation of pre-owned devices does not mean that a country allows the importation of devices that were never approved by regulators. For example, to import a medical device into the European Union (EU), the device must bear the CE Mark, which indicates that the device has been approved for sale in the EU. This applies to both new and pre-owned devices.[3] Exporters of pre-owned medical devices should thus fully investigate whether a device has been approved for sale in the target market before attempting to export the device in a pre-owned condition.

That a market permits the unrestricted importation of pre-owned medical devices does not mean that it represents a good market for pre-owned devices. Traditional buying practices favoring the latest devices, negative impressions of pre-owned equipment, and government procurement policies all affect the market. Of these, the last is perhaps the most readily quantifiable. Of the 78 markets that permit the unrestricted importation of pre-owned medical devices, 22 have laws or policies that prevent or discourage public healthcare institutions from purchasing pre-owned

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[1] This includes some double counting—information was available for the European Union, which can be considered a single market from the viewpoint of import regulations, as well as for 13 of the 15 EU member countries. Thus the count of 99 includes the EU as a whole plus 13 of its member countries.

[2] For several of these markets, however, it is safer to say that there are no reported restrictions since available reports either do not mention restrictions on pre-owned medical equipment when discussing the import regime for medical devices or simply indicate that authorities permits the importation of used equipment generally without a specific reference to medical devices.

[3] The use of the CE Mark has been required since 1995. Medical devices without the CE Mark legally sold to a customer in a EU member state before that year can be freely resold inside the EU, but identical equipment originally sold to users in other markets can not now enter the EU. In the short term, this discriminates against vendors trying to sell pre-owned devices into the EU. Over the longer run, however, this problem will be resolved as equipment approved for sale in EU-member countries before the use of the CE mark becomes too old or out-of-date to be marketable.

equipment. Although private healthcare facilities in these countries, can buy pre-owned equipment, the private healthcare sector often represent a relatively small share of the market.

**Markets that Permit the Importation of Pre-Owned Medical Devices On the Same Terms as New**

| | | | |
|---|---|---|---|
| Australia | France | Malawi | Senegal |
| Austria | Gabon | Malaysia | Singapore |
| Bahamas | Germany | Mexico* | Slovenia |
| Barbados | Ghana | Morocco | Spain |
| Belgium | Greece | Mozambique | Sri Lanka |
| Belize | Guatemala | Nepal | Sweden |
| Bolivia | Guinea | Netherlands | Switzerland |
| Botswana | Haiti | New Zealand | Taiwan |
| Cameroon | Honduras | Nicaragua | Tanzania |
| Chad | Hong Kong | Nigeria | Trinidad & Tobago |
| Chile | Hungary | Oman | Tunisia |
| Costa Rica | Iceland | Panama | Turkmenistan |
| Czech Republic | Indonesia | Paraguay | Ukraine |
| Denmark | Israel & Palestinian Auth. | Philippines | United Arab Emirates |
| Dominican Republic | Italy | Poland | United Kingdom |
| Ecuador | Jamaica | Portugal | Venezuela |
| El Salvador | Jordan | Romania | Yemen |
| Ethiopia | Kazakhstan | Russia | Zambia |
| European Union | Kyrgyzstan | Saudi Arabia | |
| Finland | Liberia | Serbia and Montenegro | |

* Mexico permits unrestricted sales to end-users, but restricts cross-border transactions between brokers, refurbishers, etc.

*Source: U.S. Department of Commerce*

**Countries with Public Procurement Policies Barring or Discouraging Purchase of Pre-Owned Equipment**

| | | | |
|---|---|---|---|
| Bahamas | Ghana | Oman | Senegal |
| Cameroon | Guinea | Panama | Sri Lanka |
| Chile | Honduras | Paraguay | Tanzania |
| Costa Rica | Indonesia | Philippines | Venezuela |
| Ecuador | Mexico | Romania | |
| El Salvador | Nicaragua | Saudi Arabia | |

*Source: U.S. Department of Commerce*

Sixteen countries—Argentina, Brazil, Canada, Colombia, Croatia, India, Japan, South Korea, Moldova, Pakistan, Peru, South Africa, Turkey, Uruguay, Uzbekistan, and Vietnam—impose restrictions of various severity on the importation of pre-owned medical devices. These restrictions include such regulations as the following:

- Taxes on pre-owned device or device over a certain age
- Ban on devices older than a certain age or beyond a set percentage of estimated useful life
- Requirement that device be refurbished by original manufacturer
- Requirement for warranties
- Requirement that parts and service be available
- Restrictive rights for importation (e.g., only by holder of registration or by end-user)
- Requirement for new licensing or approval
- Bureaucratic obstructionism not codified in law

In some cases, the restrictions are so severe as to be tantamount to a prohibition. This is often so if the regulations require that the pre-owned device be submitted to new safety licensing. Some countries do not consider the used/refurbished device to be covered by the safety approval granted to the like new device and require that it be submitted for a safety review as it if were a new type of device entering the market. It would rarely be economical for the importer to obtain a safety review for an individual piece of refurbished equipment.[4]

**Countries that Restrict the Importation of Pre-Owned Medical Equipment**

| | | | |
|---|---|---|---|
| Argentina | Croatia | Moldova | Turkey |
| Brazil | India | Pakistan | Uruguay |
| Canada | Japan | Peru | Uzbekistan |
| Colombia | Korea, South | South Africa | Vietnam |

*Source: U.S. Department of Commerce*

Only five countries—China, Egypt, Kuwait, Syria, and Thailand—appear to ban the importation of pre-owned medical equipment outright.

**Countries that Prohibit the Importation of Pre-Owned Medical Equipment**

| | |
|---|---|
| China | Syria |
| Egypt | Thailand |
| Kuwait | |

*Source: U.S. Department of Commerce*

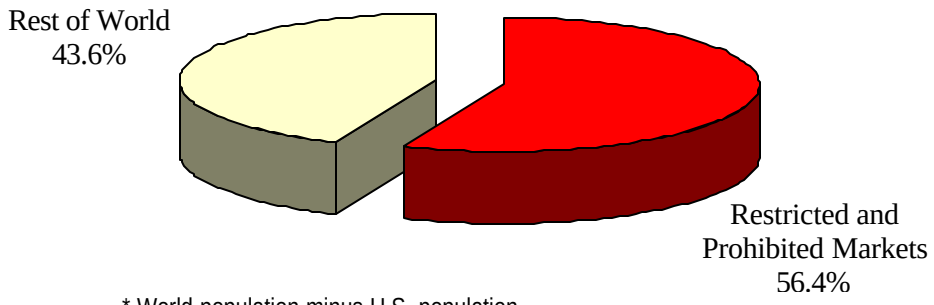
The countries included in this report are not an exhaustive listing of the world's markets. Appendix A lists 92 countries/markets for which information about import policies for pre-owned medical equipment was not available.

[4] The requirement for re-registration is sometimes confusingly described as treating used devices on the same terms as new devices, i.e., because new devices are subject to registration, so are used devices.

### *Importance of the Restricted Markets for U.S. Exporters of Pre-Owned Medical Devices*

Although only 21 countries are known to bar or restrict the importation of pre-owned medical devices, these 21 countries represent key potential markets for U.S. exporters. Not only are most of them low or middle-income countries where buyers might be attracted to the lower cost of pre-owned devices, the combined population of these 21 countries (approximately 3.3 billion people) represents 56.4 percent of the total population of the U.S. export market.[5]

**Population of the 21 Countries that Restrict or Bar Importation of Pre-Owned Medical Devices as Percent of the Potential U.S. Export Market***




* World population minus U.S. population.

*Source: U.S. Department of Commerce*

[5] Because the United States does not export to itself, the population of the U.S. export market is equal to world population minus U.S. population, about 5.8 billion.

# Market Listings

## Argentina

General Market Condition: Restricted

### *Source:* Report from CS Post (via E-Mail) 28 March 2002

The Government of Argentina places restrictions on imports of used capital goods, including medical equipment. This situation, however, implies a significant liberalization of imports of these products since 1994, after years of a virtually total ban on the importation of used medical equipment.

The principal concern of Argentine authorities regarding imports of used medical equipment is that of easing the way for well-established and qualified suppliers to enter the market, while protecting the industry from unreliable suppliers which have at different times sold badly refurbished machines or equipment without appropriate after-sale support.

Restrictions and bans on the imports of used medical equipment are established by Resolution 909/94 (issued by the Ministry of Economy in 1994) and amended by Annex II and III of the Resolution MEOSP 748/95, determining a classification of imports as follows:

- Used products which can be imported if the conditions stated below for the manufacturer, purchaser and sales representative are met (equipment certified by manufacturer, availability of after-sales servicing and availability of spare parts, purchaser must prove it is unable to purchase new equipment, etc.).
- Used products which cannot be imported
- Used and refurbished products which may be freely imported.

### *Annex II of Res 748/95: Goods That Must be Refurbished in the Country of Origin for Importation.*

[This replaced Annex I of Resolution 909/94.]

Refurbished goods must be accompanied by a certificate issued by the original manufacturer, or by a technical assessment certificate authenticated by the Commercial Section of the Argentine Embassy or the Argentine Consulate in the export country, as proof of refurbishment. Refurbishment can be done in Argentina by the importer, provided he is the end-user, and these goods can not be resold. In this case, the goods must remain in his or her possession for a period of two years, during which time donation or sale of the goods is prohibited. The end-user is subject to a proof of destination fee of 2 percent on the CIF value.

For importing refurbished goods, the foreign vendor must ensure the buyer of the availability of after-sales service and spare parts, and have an exclusive sales agent based in Argentina who will be able to implement the servicing required during the period of guarantee.

In the case of direct imports by the end-user, an official representative in-country is not required; provision of spare parts and servicing are at the importer's risk.

Reimporting of used goods, which had been previously exported temporarily in order to be repaired or to undergo any other improvement, are exempted from the refurbishment certification requirements.

## HS Codes of Items subject to Annex II of Res. MEOSP 748/95

| | | | | |
|---|---|---|---|---|
| 9018.49.30 | 9018.49.40 | 9022.13.11 | 9022.13.90 | 9022.14.90 |
| 9024.10.10 | 9024.10.20 | 9024.10.90 | 9025.19.10 | 9025.19.90 |
| 9025.80.00 | 9026.10.11 | 9026.10.19 | 9026.10.20 | 9026.20.10 |
| 9026.20.90 | 9026.80.00 | 9027.10.00 | 9027.20.20 | 9027.30.11 |
| 9027.30.19 | 9027.30.21 | 9027.30.22 | 9027.30.23 | 9027.30.29 |
| 9027.30.31 | 9027.30.39 | 9027.50.10 | 9027.50.20 | 9027.50.30 |
| 9027.50.40 | 9027.50.90 | 9027.80.11 | 9027.80.12 | 9027.80.13 |
| 9027.80.14 | 9027.80.20 | 9027.80.30 | 9027.80.90 | 9028.10.10 |
| 9028.10.90 | 9028.20.10 | 9028.20.20 | 9028.30.11 | 9028.30.19 |
| 9028.30.21 | 9028.30.29 | 9028.30.31 | 9028.30.39 | 9028.30.90 |
| 9030.20.10 | 9030.20.21 | 9030.20.22 | 9030.20.29 | 9030.20.30 |
| 9030.39.90 | 9030.40.20 | 9030.82.10 | 9030.82.90 | 9030.83.10 |
| 9030.83.20 | 9030.83.30 | 9030.83.90 | 9031.10.00 | 9031.20.10 |
| 9031.20.90 | 9031.30.00 | 9031.80.11 | 9031.80.12 | 9031.80.20 |
| 9031.80.30 | 9031.80.40 | 9031.80.50 | 9031.80.60 | 9031.80.90 |
| 9032.89.30 | | | | |

### *Annex III of Res 748/95: Goods That are Temporarily Banned from Importation*

[Replaces Annex II of Res. 909/94]

Parts and components of goods classified under Chapter 84-90 of NCM (Mercosur Common Nomenclature) are exempted from this ban, (i.e., they can be legally imported) if they have been refurbished by the original manufacturer, with a guarantee certificate. These can be imported for use paying a 28-percent import tariff, plus 5-percent statistics fee and 2-percent of proof of destination fee.

Additional exemptions from this ban are:

- Goods imported for Turnkey Projects ( under Res. MEOSP 857/94).
- Goods destined to scientific and technological research, under the system established by Decree 732/72
- Used goods which had been temporarily exported in order to be repaired or to undergo any other improvement.

## Annex III of Resolution MEOSP 748/95: Prohibited Items

| | | | | |
|---|---|---|---|---|
| 9018.11.00 | 9018.12.90 | 9018.14.00 | 9018.19.20 | 9018.19.80 |
| 9018.19.90 | 9018.20.00 | 9018.31.11 | 9018.31.19 | 9018.31.90 |
| 9018.32.11 | 9018.32.12 | 9018.32.19 | 9018.32.20 | 9018.39.10 |
| 9018.39.21 | 9018.39.22 | 9018.39.23 | 9018.39.29 | 9018.39.30 |
| 9018.39.90 | 9018.41.00 | 9018.49.11 | 9018.49.12 | 9018.49.19 |
| 9018.49.20 | 9018.49.99 | 9018.50.00 | 9018.90.10 | 9018.90.21 |
| 9018.90.29 | 9018.90.39 | 9018.90.40 | 9018.90.50 | 9018.90.91 |
| 9018.90.92 | 9018.90.95 | 9018.90.99 | 9019.10.00 | 9019.20.10 |
| 9019.20.20 | 9019.20.30 | 9019.20.40 | 9019.20.90 | 9020.00.10 |
| 9020.00.90 | 9021.11.10 | 9021.11.20 | 9021.11.90 | 9021.19.10 |
| 9021.19.20 | 9021.19.91 | 9021.19.99 | 9021.21.10 | 9021.21.90 |
| 9021.29.00 | 9021.30.11 | 9021.30.19 | 9021.30.20 | 9021.30.30 |
| 9021.30.40 | 9021.30.80 | 9021.30.91 | 9021.30.99 | 9021.40.00 |
| 9021.50.00 | 9021.90.11 | 9021.90.19 | 9021.90.80 | 9021.90.91 |
| 9021.90.92 | 9021.90.99 | 9022.13.19 | 9022.14.11 | 9022.14.12 |
| 9022.14.13 | 9022.14.19 | 9022.19.90 | 9022.21.10 | 9022.21.20 |
| 9022.21.90 | 9022.29.00 | 9022.30.00 | 9022.90.11 | 9022.90.12 |
| 9022.90.19 | 9022.90.80 | 9022.90.90 | 9023.00.00 | 9024.90.00 |
| 9025.11.10 | 9025.11.90 | 9025.90.10 | 9025.90.90 | 9026.90.10 |
| 9026.90.20 | 9026.90.90 | 9027.90.10 | 9027.90.91 | 9027.90.92 |
| 9027.90.93 | 9027.90.99 | 9028.90.10 | 9028.90.90 | 9029.10.10 |
| 9029.10.90 | 9029.20.10 | 9029.20.20 | 9029.90.10 | 9029.90.90 |
| 9030.10.10 | 9030.10.90 | 9030.39.21 | 9030.90.10 | 9030.90.20 |
| 9030.90.30 | 9030.90.90 | 9031.90.10 | 9031.90.90 | 9032.10.10 |
| 9032.10.90 | 9032.20.00 | 9032.81.00 | 9032.89.11 | 9032.89.19 |
| 9032.89.21 | 9032.89.22 | 9032.89.23 | 9032.89.24 | 9032.89.25 |
| 9032.89.29 | 9032.89.81 | 9032.89.82 | 9032.89.83 | 9032.89.84 |
| 9032.89.89 | 9032.89.90 | 9032.90.10 | 9032.90.91 | 9032.90.99 |
| 9033.00.00 | | | | |

### *Used Goods not Included in Either List*

Used goods not included in either list may be imported into Argentina. This is the case of equipment such as ultrasonic scanners and magnetic resonance imaging apparatus, among others.

### *General Import Regulations for Used Medical Equipment*

Used goods are subject to an average import fee of about 25 percent (varying according to product).

Used goods must fulfill all health control, safety, environmental, and consumer rights regulations governing importation of those same new goods.

There are no exemptions to the aforementioned Resolutions, regarding public health institutions purchasing practices, unless the equipment is donated and such exception must be expressly authorized by a specific presidential decree.

Used equipment may represent an attractive alternative for the tighter budgets of hospital and clinics as soon as the current Argentine economic and financial crisis recedes and the situation is normalized allowing for defining procurement needs.

There is currently a federal sanitary emergency due mainly to a lack of imported medical and pharmaceutical supplies. This lack of critical supplies has been partly caused by the reported difficulties of importers to re-stock supplies given the uncertain value of the peso as a result of the new floating exchange rate and temporary payment restrictions on imports that the Argentine federal government imposed in mid-December 2001. Fortunately, most medical supplies and equipment are allowed to be paid in advance under these new rules. (For a listing of the harmonized codes that can be paid for in advance as well as the required payment delays for other products, Please refer to the appendix in report entitled Argentine Import Payments Update: Payment Delays Continue dated February 26, 2002 posted at the website:

www.ComercioUSA.org/Argentina/set.asp?CONTENIDO=Editable/USExporters.html.

Due to these reasons, government authorities and the private sector are mainly concentrating their purchases on critical supplies, rather than investing on updating technology. However, the United States has always had an excellent reputation in Argentina for producing top high-technology medical equipment and for refurbishing used equipment with an outstanding level of quality. U.S. firms that find opportunities in this market may need to take additional caution, especially in ensuring payment through cash in advance or letter of credit (for products that can not be paid for in advance).

### *Mercosur HS Codes and U.S. Schedule B HS Codes*

Below is a list of Mercosur HS Codes and a list of US Schedule B HS Codes, with product description (applicable to medical equipment) to assist you in classifying your product.

**List of Mercosur HS Codes**

| HS Code | Description |
|---|---|
| 9018 | Instrumentos y aparatos de medicina, cirugia, odontologia o veterinaria, incluidos los de centellografia y demas aparatos electromedicos, asi como los aparatos para pruebas visuales<br>[Instruments and appliances used in medical/ surgical/ dental or veterinary sciences, including electro-medical and sight-testing)/ parts etc. thereof] |
| 90181 | Aparatos de electrodiagnóstico (incluidos los aparatos de exploración funcional o de vigilancia de parámetros fisiológicos: |
| 90181100 | Electrocardiógrafos |
| 90181200 | Aparatos de diagnóstico por exploración ultrasónica |
| 90181210 | Ecógrafos con análisis espectral Doppler |
| 90181290 | Los demás |
| 90181300 | Aparatos de diagnóstico de visualización por resonancia magnética |
| 90181400 | Aparatos de centellografía |

| HS Code | Description |
|---|---|
| 90181910 | Endoscopios |
| 90181920 | Audiómetros |
| 90181930 | Cámaras Gamma |
| 90181980 | Los demás |
| 90181990 | Partes |
| 901820 | |
| 90182010 | Para cirugía de córnea, que operen por láser |
| 90182090 | Los demás |
| 90183 | Jeringas, agujas,catéteres,cánulas e instrumentos similares: |
| 901831 | Jeringas, incluso con agujas |
| 9018311 | De material plástico |
| 90183111 | De capacidad inferior o igual a 2 cm3 |
| 901832 | Agujas tubulares de metal y agujas de sutura |
| 90183220 | De sutura |
| 90183910 | Agujas |
| 9018392 | Sondas, catéteres y cánulas |
| 90183921 | De caucho |
| 90183922 | Catéter de policloruro de vinilo, para embolectomía arterial |
| 90183923 | Catéter de policloruro de vinilo, para termodilución |
| 90183929 | Los demás |
| 90183930 | Lancetas para vacunación y cauterios |
| 90183990 | Los demás |
| 90184 | Los demás instrumentos y aparatos de odontología: |
| 90184100 | Tornos dentales, incluso combinados con otros equipos dentales sobre basamento común |
| 901849 | Los demás |
| 9018491 | Fresas |
| 90184911 | De carburo de tungsteno |
| 90184912 | De acero al vanadio |
| 90184919 | Las demás |
| 90184920 | Limas |
| 90184930 | Limas, Que operen por láser, para tratamiento bucal |
| 90184940 | Que operen por proyección cinética de partículas, para tratamiento bucal |
| 9018499 | Los demás |

| HS Code | Description |
|---|---|
| 90184991 | Para el diseño y la construcción de piezas cerámicas para restauración dental, computarizados |
| 90184999 | Los demás |
| 90185000 | Los demás instrumentos y aparatos de oftalmología |
| 901890 | Los demás instrumentos y aparatos |
| 90189010 | Para transfusión de sangre o infusión intravenosa |
| 9018902 | Bisturíes |
| 90189021 | Eléctricos |
| 90189029 | Los demás |
| 9018903 | Litotomos y litotritores |
| 90189031 | Litotritores por onda de choque |
| 90189039 | Los demás |
| 90189040 | Riñones artificiales |
| 90189050 | Aparatos de diatermia |
| 9018909 | Los demás |
| 90189091 | Incubadoras para bebés |
| 90189092 | Aparatos para medida de la presión arterial |
| 90189093 | Equipos para terapia intrauretral por microondas apto para el tratamiento de afecciones prostáticas, computarizados |
| 90189094 | Endoscopios |
| 90189095 | Grampas y clipes, sus aplicadores y extractores |
| 90189099 | Los demás |
| 9019 | Aparatos de mecanoterapia; aparatos para masajes; aparatos de sicotecnia; aparatos de ozonoterapia, oxigenoterapia o aerosolterapia, aparatos respiratorios de reanimacion y demas aparatos de terapia respiratoria<br>[mechano-therapy/ massage/ psychological aptitude-testing appliances and apparatus/ ozone etc. therapy and respiration apparatus/ parts and accessories] |
| 90191000 | Aparatos de mecanoterapia; aparatos para masajes; aparatos de sicotecnia |
| 901920 | Aparatos de ozonoterapia, oxigenoterapia o aerosolterapia, aparatos respiratorios de reanimación y demás aparatos de terapia respiratoria |
| 90192010 | De oxigenoterapia |
| 90192020 | De aerosolterapia |
| 90192030 | Respiratorios de reanimación |
| 90192090 | Los demás |

| HS Code | Description |
|---|---|
| 9021 | Articulos y aparatos de ortopedia, incluidas las fajas y vendajes medicoquirurgicos y las muletas; tablillas, ferulas u otros articulos y aparatos para fracturas; articulos y aparatos de protesis; audifonos y demas aparatos que lleve la propia persona o se le implanten para compensar un defecto o incapacidad<br>[orthopedic appliances/splints, etc./artificial parts of the body/hearing aids and other appliances to compensate for a defect, etc./parts etc.] |
| 90211 | Prótesis articulares y demás artículos y aparatos de ortopedia o para fracturas: |
| 902111 | Prótesis articulares |
| 90211110 | Femorales |
| 90211120 | Mioeléctricas |
| 902119 | Los demás |
| 90211910 | Artículos y aparatos de ortopedia |
| 90211920 | Artículos y aparatos para fracturas |
| 9021199 | Partes y accesorios |
| 90211991 | De artículos y aparatos de ortopedia, articulados |
| 90211999 | Los demás |
| 90212 | Artículos y aparatos de prótesis dental: |
| 902121 | Dientes artificiales. |
| 90212110 | De acrílico |
| 90212190 | Los demás |
| 90212900 | Los demás |
| 902130 | Los demás artículos y aparatos de prótesis |
| 9021301 | Válvulas cardíacas |
| 90213011 | Mecánicas |
| 90213019 | Las demás |
| 90213020 | Lentillas intraoculares |
| 90213030 | Prótesis de arterias vasculares revestidas |
| 90213040 | Prótesis mamáreas no implantables |
| 90213080 | Los demás |
| 9021309 | Partes y accesorios |
| 90213091 | Partes de prótesis modulares que reemplazan miembros |
| 90213091 | superiores o inferiores |
| 90213099 | Los demás |
| 90214000 | Audífonos, excepto sus partes y accesorios |
| 90215000 | Estimuladores cardíacos, excepto sus partes y accesorios |
| 902190 | Los demás |

| HS Code | Description |
|---|---|
| 9021901 | Aparatos que se implantan en el organismo para compensar un defecto o una incapacidad |
| 90219011 | Cardiodesfibrilador automático |
| 90219019 | Los demás |
| 90219080 | Los demás |
| 9021909 | Partes y accesorios |
| 90219091 | De estimuladores cardíacos (marcapasos) |
| 90219092 | De audífonos |
| 90219099 | Los demás |
| 9022 | Aparatos de rayos x y aparatos que utilicen radiaciones alfa, beta o gamma, incluso para uso medico, quirurgico, odontologico o veterinario, incluidos los aparatos de radiografia o radioterapia, tubos de rayos x y demas dispositivos generadores de rayos x, generadores de tension, consolas de mando, pantallas, mesas, sillones y soportes similares para examen o tratamiento<br>[X-ray, etc. apparatus/including radiography or radiotherapy apparatus/X-ray tubes and generators/ high tension generators, etc./parts and accessories] |
| 90221 | Aparatos de rayos X, incluso para uso médico, quirúrgico, odontológico o veterinario, incluidos los aparatos de radiografía o radioterapia: |
| 90221200 | Aparatos de tomografía computarizados |
| 902213 | Los demás, para uso odontológico |
| 9022131 | De diagnóstico |
| 90221311 | De tomas maxilares panorámicas |
| 90221319 | Los demás |
| 90221390 | Los demás |
| 902214 | Los demás, para uso médico, quirúrgico o veterinario |
| 9022141 | De diagnóstico |
| 90221411 | Para mamografía |
| 90221412 | Para angiografía |
| 90221413 | Para densitometría ósea, computarizado |
| 90221419 | Los demás |
| 90221490 | Los demás |
| 902219 | Para otros usos |
| 90221910 | Espectrómetros o espectrógrafos de rayos X |
| 90221990 | Los demás |
| 90222 | Aparatos que utilicen radiaciones alfa, beta o gamma, incluso para uso médico, quirúrgico, odontológico o veterinario, incluidos los aparatos de radiografía o radioterapia: |
| 902221 | Para uso médico, quirúrgico, odontológico o veterinario |

| HS Code | Description |
|---|---|
| 90222110 | Aparatos de radiocobalto (bomba de cobalto) |
| 90222120 | Aparatos de gammaterapia |
| 90222190 | Los demás |
| 90222900 | Para otros usos |
| 90223000 | Tubos de rayos X |
| 902290 | Los demás, incluidas las partes y accesorios |
| 9022901 | Aparatos |
| 90229011 | Generadores de tensión |
| 90229012 | Pantallas radiológicas |
| 90229019 | Los demás |
| 90229080 | Los demás |
| 90229090 | Partes y accesorios de aparatos de rayos X |
| 90230000 | Instrumentos, aparatos y modelos concebidos para demostraciones (por ejemplo: en la enseñanza o exposiciones), no susceptibles de otros usos<br>[instruments/ apparatus and models/ designed for demonstrational purposes/ unsuitable for other uses] |
| 9024 | Maquinas y aparatos para ensayos de dureza,traccion,compresion, elasticidad u otras propiedades mecanicas de materiales (por ejemplo: metal, madera, textil, papel, plastico). [machines and appliances for testing the mechanical properties of materials (hardness/ strength etc. of metal/ wood/ paper etc.)/ parts and accessories] |
| 902410 | Máquinas y aparatos para ensayo de metales |
| 90241010 | Para ensayos de tracción o de compresión |
| 90241020 | Para ensayos de dureza |
| 90241090 | Los demás |
| 902480 | Las demás máquinas y aparatos |
| 9024801 | Máquinas y aparatos para ensayos de textiles |
| 90248011 | Automáticos, para hilados |
| 90248019 | Los demás |
| 90248020 | Máquinas y aparatos para ensayos de papel, cartón, linóleo y plástico o caucho flexibles |
| 90248090 | Los demás |
| 90249000 | Partes y accesorios |
| 9025 | Densimetros, areometros, pesaliquidos e instrumentos flotantes similares, termometros, pirometros, barometros, higrometros y sicrometros, aunque sean registradores, incluso combinados entre si<br>[hydrometers/ thermometers/ pyrometers/ barometers/ hygrometers and psychrometers etc./ parts and accessories thereof] |
| 90251 | Termómetros y pirómetros,sin combinar con otros instrumentos: |

| HS Code | Description |
|---|---|
| 902511 | De líquido, con lectura directa |
| 90251110 | Termómetros clínicos |
| 90251190 | Los demás |
| 902519 | Los demás |
| 90251910 | Pirómetros ópticos |
| 90251990 | Los demás |
| 90258000 | Los demás instrumentos |
| 902590 | Partes y accesorios |
| 90259010 | De termómetros |
| 90259090 | Los demás |
| 9026 | Instrumentos y aparatos para la medida o control del caudal, nivel, presion u otras caracteristicas variables de liquidos o gases (por ejemplo: caudalimetros, indicadores de nivel, manometros, contadores de calor), excepto los instrumentos y aparatos de las partidas nos 90.14, 90.15, 90.28 o 90.32.<br>[instruments and apparatus for measuring or checking the flow/ level/ pressure or other variables of liquids or gases/ nesoi/ parts and accessories] |
| 902610 | Para medida o control del caudal o nivel de líquidos |
| 9026101 | Para medida o control de caudal |
| 90261011 | Medidores - transmisores electrónicos, que funcionen por el principio de inducción electromagnética |
| 90261019 | Los demás |
| 90261020 | Para medida o control de nivel |
| 902620 | Para medida o control de presión |
| 90262010 | Manómetros |
| 90262090 | Los demás |
| 90268000 | Los demás instrumentos y aparatos |
| 902690 | Partes y accesorios |
| 90269010 | De instrumentos y aparatos para medida o control de nivel |
| 90269020 | De manómetros |
| 90269090 | Los demás |
| 9027 | Instrumentos y aparatos para analisis fisicos o quimicos (por ejemplo: polarimetros, refractometros, espectrometros, 'analizadores de gases o humos); instrumentos y aparatos para' ensayos de viscosidad, porosidad, dilatacion, tension superfi- cial o similares o para medidas calorimetricas, acusticas o 'fotometricas<br>[incluidos los exposimetros); microtomos. (instruments and apparatus for physical or chemical analysis/ including checking viscosity/ expansion/ heat/ sound/ light etc./ microtomes/ parts etc.] |
| 90271000 | Analizadores de gases o humos |

| HS Code | Description |
|---|---|
| 902720 | Cromatógrafos e instrumentos de electroforesis |
| 9027201 | Cromatógrafos |
| 90272011 | De fase gaseosa |
| 90272012 | De fase líquida |
| 90272019 | Los demás |
| 90272020 | Instrumentos de electroforesis |
| 902730 | Espectrómetros, espectrofotómetros y espectrógrafos que utilicen radiaciones ópticas (UV, visibles, IR) |
| 9027301 | Espectrómetros |
| 90273011 | De emisión óptica (emisión atómica) |
| 90273019 | Los demás |
| 9027302 | Espectrofotómetros |
| 90273021 | De radiaciones UV, visibles o IR |
| 90273022 | De absorción atómica |
| 90273023 | De emisión óptica (emisión atómica) |
| 90273029 | Los demás |
| 9027303 | Espectrógrafos |
| 90273031 | De emisión óptica (emisión atómica) |
| 90273039 | Los demás |
| 90274000 | Exposímetros |
| 902750 | Los demás instrumentos y aparatos que utilicen radiaciones ópticas (UV, visibles, IR) |
| 90275010 | Colorímetros |
| 90275020 | Fotómetros |
| 90275030 | Refractómetros |
| 90275040 | Sacarímetros |
| 90275090 | Los demás |
| 902780 | Los demás instrumentos y aparatos |
| 9027801 | Calorímetros, viscosímetros, densitómetros y pehachímetros |
| 90278011 | Calorímetros |
| 90278012 | Viscosímetros |
| 90278013 | Densitómetros |
| 90278014 | Pehachímetros |
| 90278020 | Espectrómetros de masa |
| 90278030 | Polarógrafos |
| 90278090 | Los demás |

| HS Code | Description |
|---|---|
| 902790 | Micrótomos; partes y accesorios |
| 90279010 | Micrótomos |
| 9027909 | Partes y accesorios |
| 90279091 | De espectrómetros de emisión óptica (emisión atómica) |
| 90279092 | De espectrógrafos de emisión óptica (emisión atómica) |
| 90279093 | De polarógrafos |
| 90279099 | Los demás |
| 9028 | Contadores de gas, liquido o electricidad, incluidos los de calibracion<br>[gas/ liquid or electricity supply or production meters/ including calibrating meters therefor/ parts and accessories thereof] |
| 902810 | Contadores de gas |
| 90281010 | De gas natural comprimido, electrónicos |
| 90281090 | Los demás |
| 902820 | Contadores de líquido |
| 90282010 | De peso inferior o igual a 50 kg |
| 90282020 | De peso superior a 50 kg |
| 902830 | Contadores de electricidad |
| 9028301 | Monofásicos para corriente alterna |
| 90283011 | Numéricos (digitales) |
| 90283019 | Los demás |
| 9028302 | Bifásicos |
| 90283021 | Numéricos (digitales) |
| 90283029 | Los demás |
| 9028303 | Trifásicos |
| 90283031 | Numéricos (digitales) |
| 90283039 | Los demás |
| 90283090 | Los demás |
| 902890 | Partes y accesorios |
| 90289010 | De contadores de electricidad |
| 90289090 | Los demás |
| 9029 | Los demas contadores (por ejemplo:cuentarrevoluciones,contado- res de produccion, taximetros, cuentakilometros, podometros); velocimetros y tacometros, excepto los de las partidas nos ‘90.14 o 90.15; estroboscopios.<br>[revolution and production counters/ taximeters etc./ speedometers and tachometers nesoi/ stroboscopes/ parts and accessories thereof] |
| 902910 | Cuentarrevoluciones, contadores de producción, taxímetros, cuentakilómetros, podómetros y contadores similares |

| HS Code | Description |
|---|---|
| 90291010 | Cuentarrevoluciones, contadores de producción o de horas de trabajo |
| 90291090 | Los demás |
| 902920 | Velocímetros y tacómetros; estroboscopios' |
| 90292010 | Velocímetros y tacómetros |
| 90292020 | Estroboscopios |
| 902990 | Partes y accesorios |
| 90299010 | De velocímetros y tacómetros |
| 90299090 | Los demás |
| 9030 | Osciloscopios, analizadores de espectro y demas instrumentos y aparatos para medida o control de magnitudes electricas; instrumentos y aparatos para medida o deteccion de radiaciones alfa, beta, gamma, x, cosmicas o demas radiaciones ionizantes<br>[oscilloscopes/ spectrum analyzers etc. for measuring etc. electrical quantities/ nesoi/ devices for measuring etc. ionizing radiations/ parts etc.] |
| 903010 | Instrumentos y aparatos para medida o detección de radiaciones ionizantes |
| 90301010 | Medidores de radiactividad |
| 90301090 | Los demás |
| 903020 | Osciloscopios y oscilógrafos catódicos |
| 90302010 | Osciloscopios numéricos (digitales) |
| 9030202 | Osciloscopios analógicos |
| 90302021 | De frecuencia superior o igual a 60 MHz |
| 90302022 | Vectorscopio |
| 90302029 | Los demás |
| 90302030 | Oscilógrafos |
| 90303 | Los demás instrumentos y aparatos para medida o control de tensión, intensidad, resistencia o potencia, sin dispositivo registrador: |
| 90303100 | Multímetros |
| 903039 | Los demás |
| 9030391 | Voltímetros |
| 90303911 | Numéricos (digitales) |
| 90303919 | Los demás |
| 9030392 | Amperímetros |
| 90303921 | Del tipo de los utilizados en vehículos automotores |
| 90303929 | Los demás |
| 90303990 | Los demás |
| 903040 | Los demás instrumentos y aparatos, especialmente concebidos para técnicas de telecomunicación (por ejemplo: hipsómetros, kerdómetros, distorsiómetros, sofómetros) |

| HS Code | Description |
|---|---|
| 90304010 | Analizadores de protocolo |
| 90304020 | Analizadores de nivel selectivo |
| 90304030 | Analizadores numéricos (digitales) de transmisión |
| 90304090 | Los demás |
| 90308 | Los demás instrumentos y aparatos: |
| 903082 | Para medida o control de obleas (‘‘wafers’’) o dispositivos, semiconductores |
| 90308210 | De prueba de circuitos integrados |
| 90308290 | Los demás |
| 903083 | Los demás, con dispositivo registrador |
| 90308310 | De prueba de continuidad de circuitos impresos |
| 90308320 | De prueba automática de circuitos impresos con sus |
| 90308320 | componentes montados |
| 90308330 | De medida de parámetros característicos de señales de televisión o video |
| 90308390 | Los demás |
| 903089 | Los demás |
| 90308910 | Analizadores lógicos de circuitos numéricos (digitales) |
| 90308920 | Analizadores de espectro de frecuencia |
| 90308930 | Frecuencímetros |
| 90308940 | Fasímetros |
| 90308990 | Los demás |
| 903090 | Partes y accesorios |
| 90309010 | De instrumentos y aparatos de la subpartida no 9030.10 |
| 90309020 | De instrumentos y aparatos de las subpartidas nos 9030.31 ó 9030.39 |
| 90309030 | De instrumentos y aparatos de las subpartidas nos 9030.82 ó 9030.83 |
| 90309090 | Los demás |
| 9031 | Instrumentos, aparatos y maquinas de medida o control, no ‘expresados ni comprendidos en otra parte de este capitulo;’ proyectores de perfiles.<br>[measuring or checking instruments/ appliances and machines/ nesoi/ profile projectors/ parts and accessories thereof] |
| 90311000 | Máquinas para equilibrar piezas mecánicas |
| 903120 | Bancos de pruebas |
| 90312010 | Para motores |
| 90312090 | Los demás |
| 90313000 | Proyectores de perfiles |
| 90314 | Los demás instrumentos y aparatos, ópticos: |

| HS Code | Description |
|---|---|
| 90314100 | Para control de obleas (‘‘wafers’’) o dispositivos,’ semiconductores, o control de máscaras o retículas utilizadas en la fabricación de dispositivos semiconductores |
| 90314900 | Los demás |
| 903180 | Los demás instrumentos, aparatos y máquinas |
| 9031801 | Dinamómetros y rugosímetros |
| 90318011 | Dinamómetros |
| 90318012 | Rugosímetros |
| 90318020 | Máquinas para medición tridimensional |
| 90318030 | Metros patrones |
| 90318040 | Aparatos digitales de uso en vehículos automóviles para medida e indicación de múltiples magnitudes, tales como: velocidad media, consumos instantáneo y medio y autonomía (computadores de a bordo) |
| 90318050 | Aparatos para análisis de textiles, computarizados |
| 90318060 | Celdas de carga |
| 90318090 | Los demás |
| 903190 | Partes y accesorios |
| 90319010 | De bancos de pruebas |
| 90319090 | Los demás |
| 9032 | Instrumentos y aparatos para regulacion o control automaticos<br>[automatic regulating or controlling instruments and apparatus/ parts and accessories thereof] |
| 903210 | Termostatos |
| 90321010 | De expansión de fluídos |
| 90321090 | Los demás |
| 90322000 | Manostatos (presostatos) |
| 90328 | Los demás instrumentos y aparatos: |
| 90328100 | Hidráulicos o neumáticos |
| 903289 | Los demás |
| 9032891 | Reguladores de voltaje |
| 90328911 | Electrónicos |
| 90328919 | Los demás |
| 9032892 | Controladores electrónicos del tipo de los utilizados en |
| 9032892 | vehículos automóviles |
| 90328921 | De sistemas antibloqueo de freno (ABS) |
| 90328922 | De sistemas de suspensión |
| 90328923 | De sistemas de transmisión |

| HS Code | Description |
|---|---|
| 90328924 | De sistemas de ignición |
| 90328925 | De sistemas de inyección |
| 90328929 | Los demás |
| 90328930 | Equipamiento digital para control de vehículos ferroviarios |
| 9032898 | Los demás para la regulación o el control de magnitudes no eléctricas |
| 90328981 | De presión |
| 90328982 | De temperatura |
| 90328983 | De humedad |
| 90328984 | De velocidad de motores eléctricos por variación de frecuencia |
| 90328989 | Los demás |
| 90328990 | Los demás |
| 903290 | Partes y accesorios |
| 90329010 | Circuitos impresos con componentes eléctricos o electrónicos montados |
| 9032909 | Los demás |
| 90329091 | De termostatos |
| 90329099 | Los demás |
| 90330000 | [parts and acce. (not specified or included elsewhere in this chapter) for machines/ appliances/ instruments or apparatus of chapter 90] |

## List of U.S. Schedule B HS Codes

| HS Code | Description |
|---|---|
| 9018110040 | Electrocardiographs |
| 9018110080 | Parts and accessories for electrocardiographs |
| 9018194000 | Apparatus, functional exploratory examination& pts |
| 9018198020 | Patient monitoring system, temperature, pulse,etc |
| 9018198030 | Basal metabolism and blood pressure apparatus |
| 9018198035 | Electroencephalographs and electromyographs |
| 9018198045 | Ultrasonic scanning apparatus |
| 9018198050 | Other electro-diagnostic apparatus, nesoi |
| 9018198060 | Parts&accessories for electro-diagnostic apparatus |
| 9018200000 | Ultraviolet or infrared ray apparatus, & pts & acc |
| 9018310040 | Hypodermic syringes, with or without their needles |
| 9018310080 | Syringes, with or without their needles, nesoi |
| 9018310090 | Pts for syrings, with or without their needles |
| 9018320000 | Tubular metal needles & needles for sutures &parts |

| HS Code | Description |
|---|---|
| 9018390030 | Bougies, catheters, drains & sondes & pts & access |
| 9018390050 | Cannulae and the like and part and accessories |
| 9018410000 | Dental drill engines and parts and accessories |
| 9018490000 | Inst & appln for dental science, & pts & acc, nesoi |
| 9022190000 | Apparatus base on x-ray for oth use,ex medical,etc |
| 9022294000 | Appts, alpha,beta,etc radiation for smoke detector |
| 9022298000 | Appts, alpha,beta,etc radiation for oth use, nesoi |
| 9024100000 | Machines and appliances for testing metals |
| 9024800000 | Machine&appliance,test hardness,strength,etc,nesoi |
| 9024900000 | Pts, machine & appln, test hardness/strength, etc |
| 9025112000 | Clinical thermometers liquid-filled |
| 9025114000 | Thermometers liquid-filled, direct reading, nesoi |
| 9025194000 | Pyrometers not combined with other instruments |
| 9025198040 | Clinical thermometers, nt combind w oth inst,nesoi |
| 9025198080 | Thermometers, nt combined with oth inst, nesoi |
| 9025200000 | Barometers, not combined with other instruments |
| 9025800000 | Hydrometers, hygrometers,psychyrometers,etc,nesoi |
| 9025900000 | Pts, hydrometers,therometers,pyrometers, etc |
| 9026105000 | Flow meter for meas/checking flow/level of liquids |
| 9026107000 | Inst & apprts, meas/check flow/level of liq, nesoi |
| 9026200000 | Inst & apprts, measuring/checking pressure |
| 9026800000 | Inst measure/checking variable of liq/gases, nesoi |
| 9026900000 | Pts, inst & apprts measure/check variables liq/gas |
| 9027100000 | Gas or smoke analysis apparatus |
| 9027202000 | Gas chromatographs |
| 9027204040 | Electrical electrophoresis instruments |
| 9027205000 | Liquid chromatographs |
| 9027209000 | Chromatographs & electrophoresis inst, nesoi |
| 9027304040 | Spectrophotometers using optical rad nonelectrical |
| 9027304080 | Elec spectrometers & spectrographs etc., opt radtn |
| 9027308020 | Spectroscopes using optical radiations, nonelec |
| 9027308080 | Spectrometers & spectrograph,opt rad,nonelec,nesoi |
| 9027400000 | Exposure meters |
| 9027502000 | Thermal analysis instruments and apparatus |

| HS Code | Description |
|---|---|
| 9027504050 | Photometers |
| 9027505000 | Oth chem analysis instruments & apparatus, nesoi |
| 9027509000 | Inst,physical/chem analysis opt radiation,nesoi |
| 9027801000 | Nuclear magnetic resonances inst exc heading 9018 |
| 9027802000 | Mass spectrometers |
| 9027803100 | Electrochemical instruments and apparatus, |
| 9027803200 | Chemical instruments and apparatus, nesoi |
| 9027803500 | Phys analysis inst, exc optical radiations, nesoi |
| 9027808000 | Inst, measuring/checking viscosity etc, nesoi |
| 9027902000 | Microtomes |
| 9027904030 | Pts & access of schb 9027.30.4040 & 9027.30.4080 |
| 9027904040 | Pts & accessories of articles of schb 9027.40.0000 |
| 9027904070 | Pts & access of inst & appts for physical/chem etc |
| 9030100000 | Inst for measuring/detecting ionizing radiations |
| 9030200000 | Cathode-ray oscilloscopes&cathode-ray oscillograph |
| 9030310000 | Multimeters |
| 9030390040 | Apparatus to test voltage or current or resistance |
| 9030390080 | Inst&appts for measuring/checking power, nesoi |
| 9030400000 | Oth inst, specially designed for telecommunication |
| 9030810040 | Inst to check semiconduct wafers &such that record |
| 9030810080 | Inst & app with recording device, nesoi |
| 9030890080 | Inst,measuring/checking electrical quantitie,nesoi |
| 9030904000 | Parts for articles of subheading 9030.10 |
| 9030908010 | Parts and access for article of subhdg 9030.20 |
| 9030908020 | Pts & access of articles of schb subhdg 9030.31 |
| 9030908030 | Pts & access of artcl of schb subhdg 9030.39 |
| 9030908040 | Parts & access of articles of schb subhdg 9030.40 |
| 9030908050 | Parts and access of arti of subhdg 9030.82 or .83 |
| 9030908060 | Pts & access of articles of schb subhdg 9030,nesoi |
| 9031100000 | Machines for balancing mechanical parts |
| 9031200000 | Test benches |
| 9031300000 | Profile projectors |
| 9031400020 | Optical inst and app for inspecting photomasks |
| 9031400040 | Optical inst for inspecting semiconductor wafers |

| HS Code | Description |
|---|---|
| 9031400060 | Optical inst for inspecting semicond devices nesoi |
| 9031400080 | Optical instruments and appliances nesoi |
| 9031800060 | Equip, testing elec characteristics of engines |
| 9031800070 | Equip, testing exc elec characteristics of engines |
| 9031800080 | Measure/check inst,appln&machines,nesoi in chap 90 |
| 9031900000 | Pts, of mach nesoi in this chap,& profile projectr |

### *Source:* Industry Sector Analysis, *Medical Equipment*, 19 October 2001

If possible, disposable products are normally reused as a cost-saving measure. This is possible because governmental and institutional regulations are not as strict as in the U.S. However, with free-market reforms and greater competition, disposable products have recently begun to be discarded at a faster rate, causing the demand for new supplies to increase somewhat.

To protect the health of its citizens, Argentina has restricted imports of used medical equipment. According to Resolution 909, issued by the Ministry of Economy in 1994, used goods must be refurbished for importation into Argentina. Moreover, goods must be accompanied by either a certificate issued by the original manufacturer or a technical assessment certificate authenticated by the Argentine Embassy or Consulate in the export country as proof of refurbishment.

Resolution 909 also requires that an official representative, appointed by the original manufacturer ensure the availability of spare parts and servicing in Argentina. An official local representative is not required in order to import used goods directly into Argentina, although the end-user (who has to maintain possession of the items for two years) is solely responsible for the provision of spare parts and servicing.

## Australia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 28 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

There are no specific tariffs that apply to used or refurbished medical equipment that do not apply to new medical equipment.

Any used or refurbished medical equipment must comply with the same regulations as new medical equipment. This includes any relevant Australian standards and listing or registration with the Therapeutic Goods Administration (TGA). For information on medical regulations and the TGA, contact:

The Information Officer, Conformity Assessment Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Tel: 61 2 6232 8673
Fax: 61 2 6232 8785
Email: glenn.street@health.gov.au
Website: www.health.gov.au/tga

*Can public health institutions buy used or refurbished medical devices?*

Health institutions are able to purchase used/refurbished medical equipment with no restrictions. Preference is given to products that come with quality assurance and warranties. Suppliers of used/refurbished medical equipment are more likely to distribute products for which there are available spare parts.

However, since the Australian market for medical devices is mature and consumers are sophisticated, there is little demand for technologically obsolete devices. It appears that much of the supply of used equipment is being met by local health institutions with only a small amount being imported. Therefore, there has been little or no increase in suppliers or market for used equipment over the past few years. Major teaching hospitals are unlikely to expose themselves to the increased risk of purchasing used goods. Given the current strength of the U.S. dollar, the economic viability of importing used equipment of suitable quality into Australia is considered questionable at this time.

As an example, New South Wales Health, the primary purchaser of medical equipment for public hospitals in the state of New South Wales, has advised that they have not entertained any arrangements for used equipment recently.

*Is there a market for used or refurbished medical devices?*

Demand for used medical equipment is limited. There is technically a market for used or recycled equipment, however, the market is not a commercially thriving one. This is because hospitals and hospital groups sell used equipment among themselves and the equipment moves down the 'food chain' from major hospitals to small private hospitals and out-patient clinics.

Technical advances and the desire to have the latest and best equipment, even in small hospitals, is making used equipment redundant. An export market of used equipment is developing with Australian distributors exporting to Asia, the Pacific Islands and Papua New Guinea. In addition, some equipment is being exported to overseas locations through church groups and organizations such as Rotary International.

*If there is a market, what types of used or refurbished medical equipment are in greatest demand?*

The market for used or refurbished medical equipment in Australia is small, with limited prospects for U.S. suppliers. Best prospects lie in the low-technology sector of the market such as furniture (for example, beds), wheelchairs, and rehabilitation equipment.

## Austria

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via Cable) October 22, 1998

There are no restrictions on the import of used equipment per se in Austria. All imports of used equipment are treated the same as new. This means that they carry the same duty and are required to be tested and marked with the European 'CE' mark before being installed.

[This cable generally addresses manufacturing and agricultural equipment; applicability of these comments to medical equipment is uncertain.]

## Bahamas

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

### *Source:* Report from CS Post (via Cable) 4 April 2001

The Bahamas Ministry of Health provided the following information in response to questions regarding the importation of used medical equipment.

The Government of the Bahamas applies the same restrictions to both used and new medical equipment. (Importation of new or used medical equipment is subject to a 42 percent customs duty.)

It is not a policy of the Ministry of Health to purchase used and/or refurbished medical equipment, implements, or devices. Bahamian public and private sector health institutions prefer to purchase new equipment.

## Barbados

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 6 June 2000 (Information confirmed 29 March 2002)

There are currently no restrictions on the importation of used and refurbished medical equipment into Barbados.

The import duty applied to used or refurbished medial equipment is the same as applied to new medical equipment. The tariff rate on medical equipment varies between 5 percent to 20 percent depending on the type of medical equipment. There is also a 1 percent environmental levy and a 15-percent value-added tax applied to imports of medical equipment.

Ministry of Health officials advise that there are no restrictions on the importation of used medical or refurbished equipment by public health institutions. However, based on past experience relating to reliability and the conditions of used medical equipment, it is the practice of the Ministry of Health to purchase new medical equipment. The purchase of used medical equipment also does not adhere to the procurement practices of the Government of Barbados.

Private sector health care professionals can purchase used or refurbished medical equipment. However, the Ministry of Health needs to be advised of all purchases of used medical equipment being imported into Barbados.

There are no statistics available on the market for used or refurbished medical equipment in Barbados. Based on the strong preference by government and private sector health care professionals to purchase new medical equipment, we do not foresee much market potential for used medical equipment in Barbados.

# Belgium

General Market Condition: No Restrictions, but CE Mark is Required
*See also the entry for the European Community.*

## *Source:* Report from CS Post (via E-Mail) 26 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment?*

No. Used medical equipment is treated identically as new medical equipment regarding CE mark and import duties.

*Can public health institutions buy used or refurbished medical devise?*

Yes, but hospitals are more reluctant to purchase used equipment or to reuse medical devices because of liability issues. In Belgium, used or refurbished equipment is sometimes used to train students. A lot of used and refurbished equipment is exported to developing countries in Africa and the former eastern countries.

*Is there a market for used or refurbished medical devices?*

Yes, if the refurbished medical devices are of a superior quality compared with the existing medical devices. Belgian hospitals have the reputations of using very high-tech medical equipment.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

High-tech equipment.

# Belize

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via E-Mail) 5 April 2002

Based on information supplied by Belize's Assistant Comptroller of Customs, Everard Lopez:

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

There are no special restrictions or tariffs applied to used and refurbished medical equipment that are imported into Belize. A 10-percent import duty is levied on most of the new and used/refurbished medical equipment imported into the country. A very small percentage is exempted from import duty, a list of which may be obtained from the Belize Customs Department. Local importers also pay an eight percent sales tax and a one-percent environmental tax on all new and used/refurbished medical equipment.

*Can public health institutions buy used or refurbished medical devices?*

Public Health institutions and individual companies can and do buy used or refurbished medical devices.

*Is there a market for used or refurbished medical devices?*

Recent trade figures indicate that there is a growing market in Belize for used and refurbished medical devices.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

Based on recent import entry data, used lamps, chairs and optical projectors for eye examinations are in the greatest demand in Belize. Data indicate also that used medical equipment, which include universal radios, graph units, monographic optical delivery beds, and konica with stands are also in great demand.

## Bolivia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 21 March 2002

The Government of Bolivia does not impose restriction on the importation of any kind of used/refurbished medical equipment into Bolivia.

All imports of used equipment are treated the same as new. However, one of the two official Bolivian government inspection companies, SGS or Inspectorate, must determine the real FOB value of the equipment, before shipping to Bolivia, for which they charge 1.92 percent of the FOB cost of the imported product. The importer must then pay the respective customs tariff as if a new product, which is 10 percent of the CIF price, plus other taxes and duties, which amounts to about 28 percent of the CIF value. Products that are classified as 'capital goods' pay a duty rate of only 5 percent. Most industrial equipment falls into this category, however, medical equipment, books, and publications, pay only a 2 percent Rate.

The only restrictions on used products are for used clothing without a sanitary certificate (fumigation) from the country of origin (except in personal baggage). There is a total prohibition for the importation of used hats, shoes, underwear and lingerie.

Public health institutions can buy used or refurbished medical devices. To do so, they normally call for public bids with a 30 to 45 day deadline to present proposals. Consequently, it is advantageous for U.S. companies to have a local representative to keep them abreast of new projects in the public sector.

The market for used equipment has always been open for U.S. products. In fact, a number of small businesses are always looking for suppliers of used/refurbished equipment because they find U.S. products more attractive for their quality, easy access to spare parts, and quick maintenance if required.

There has been special preference for used/refurbished medical equipment, such as medical diagnosis system, optical instruments, anesthesia apparatuses, operating room furniture, patient room furniture, other hospital furniture, and surgical instruments and apparatuses.

# Brazil

General Market Condition: Restricted

## *Source:* Brazil: Country Commercial Guide FY 2002

### *Best Prospects for Non-Agricultural Goods and Services—Sector: Medical Equipment and Devices*

#### *A New Market for Refurbished Equipment*

Brazil approved a law that regulates the import of refurbished medical equipment. Companies that are interested in this niche have to comply to a rigid set of guidelines, including, date of refurbishment, accurate adjustment & calibration. The refurbished equipment must meet the exact same performance of new equipment. Also, the manufacturer must provide technical assistance in Brazil or designate a local representative to provide the service.

### *Trade Barriers, including tariffs, non-tariff barriers and import taxes—Import Licenses*

#### *Automatic License*

As a general rule, Brazilian imports are subject to the 'automatic import license' process. This procedure requires that the Brazilian importer submits information concerning each import, including description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc. This information will be used for purposes of preparing the 'Import Declaration' (locally known as the DI). Subsequently, all information is fed into Brazil's customs computer system known as the SISCOMEX. The Brazilian Foreign Trade Secretariat (SECEX) is the government agency responsible for granting import licenses.

#### *Non-Automatic License (LI)*

Whenever imports are subject to the Non-Automatic License (LI) regime, the importer must provide information concerning each shipment to Brazilian customs authority either prior to shipment or prior to customs clearance. The required information includes a description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc.

- Prior to Customs Clearance: Products imported under the drawback regime, as well as imports destined to the free trade zones and the National Council for Scientific and Technological Development.
- Prior to Shipment Clearance: Products subject to special controls from SECEX or which require approvals from other Brazilian government agencies. Such products may include: used products in general, products that enjoy import tariff reductions, imports that do not involve payment from importer to the exporter -- e.g., samples, donations, temporary admission, psychotherapeutic drugs, products for human or veterinary research; weapons and related products, radioactive products and rare earth metal compounds, crude oil, oil derivatives or other petroleum derivatives, anti-hemophilic serum, medications with plasma and human blood, products that may be harmful to the environment -- e.g., CFC, mailing machines, stamp selling machines, airplanes, etc.

Shortly after feeding the SISCOMEX system information concerning a specific shipment, the SISCOMEX system will indicate whether or not a 'non-automatic import license' is required.

### *Source:* Report from CS Post (via E-Mail) 17 May 2001

On February 15th 2001, ANVISA (National Health Administration Agency) published resolution RDC nº 25, which regulates imports of used medical equipment. The resolutation imposes strict requirements that used equipment must meet before it can be imported into the country. Some of the requirements include:

- Registration with Brazil's *Vigilancia Sanitaria* agency. If the product does not require such registration, submit evidence to support your claim;
- Obtain an import license. The license must state the country of origin, detailed information of product, name of manufacturer, model and technical specifications;
- The equipment must be thoroughly cleaned and refurbished;
- All parts and pieces subject to wear and tear must be replaced;
- The equipment must be professionally calibrated to meet original specifications which must be certified by the original manufacturer;
- New labels must be affixed and an instruction manual must be provided;
- Submit the year the equipment was refurbished;
- The equipment must pass thorough quality control tests; and
- Make spare parts and components available in Brazil during the useful life of the equipment.

There are severe penalties for companies that do not follow the requirements listed above, including assessment of stiff fines and even confiscation of the equipment. Therefore, it is critical that U.S. exporters of used medical equipment coordinate closely the transaction with the Brazilian importer. We also strongly advise that U.S. companies obtain the services of a reputable Brazilian customs brokerage firm with significant experience related to imports of medical equipment.

For further information please contact

Jefferson Oliveira
Business Development Specialist
Rua Estados Unidos, 1812
01427-002 - Sao Paulo – SP
Phone: 55-11-3897-4038
Fax: 55-11-3085-9626
E-mail: Jefferson.Oliveira@mail.doc.gov

## Botswana

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 12 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

No. Used medical equipment imports are subject to the same tariffs as new medical equipment. Used medical equipment that comes into Botswana as donations to the public

hospitals/institutions is generally exempted from tariffs. There are no specific restrictions on the importation of used medical equipment, but at the point of customs clearance, the equipment is subject to rejection should if found to be significantly out-of-date.

*Can public health institutions buy used or refurbished medical devices?*

Yes.

*Is there a market for used and refurbished medical devices?*

Importation of used medical equipment is minimal. Most of the imported used or refurbished medical devices imported to Botswana are donations to public hospitals/institutions. Generally speaking, medical equipment in Botswana is usually purchased new by the Ministry of Health through the government tender process.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

Not applicable.

## Cameroon

General Market Condition: No Restrictions, but Not Accepted in Public Tenders for Public Health Facilities

### *Source:* Report from CS Post (via E-Mail) 28 March 2002

According to Mr. Charles Tawamba, Technical Adviser to the Minister of Economy and Finance. (prior to his current post, he was the Legal Affairs Director in the Ministry of Commerce and Industrial Development (MINDIC):

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

There are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment.

*Can public health institutions buy used or refurbished medical devices?*

Public health institutions can not usually buy used or refurbished medical devices on a government budget. The health strategy being planned by the Government of Cameroon will pass management of district hospitals to a community-based board of directors. The community, after surveying its needs, will decide where and when to acquire medical devices.

*Is there a market for used or refurbished medical devices?*

There is an important market for used or refurbished medical devices. Cameroon is slowing emerging from a deep economic crisis that resulted in reduced spending on health. Since Cameroon is eligible (Decision Point reached) for the Highly Indebted Poor country initiative, funds previously used to repay its debt will be reorientated toward health and education spending and will result in increased spending on medical devises.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

In the countryside, a dearth of medical equipment of all sorts exists. Rural hospitals have a critical need for all types of medical equipment, particularly laboratory tests equipment, hospitalization equipment, surgical equipment, and feeding tubes and other intubation products.

### *Source:* Report from CS Post (via Cable) 13 March 2001

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

There are no restrictions on the import of used/refurbished equipment in Cameroon. However, used equipment imported from the United States is often penalized due to overvaluation at the Cameroonian customs when customs duties are assessed. The duty on used equipment imported from the United States is calculated on the basis of the price of similar equipment imported from European markets, not on the selling price in the United States

*Can public health institutions buy used or refurbished Medical devices?*

Used medical equipment is not accepted in public-sector tenders for the supply of equipment and materials to government-owned public health facilities. However, private clinics and religious hospitals have no restriction on purchasing such equipment.

*Is there a market for used of refurbished devices?*

The Cameroonian market for used medical equipment is relatively small. Germany has the largest market share with its Siemens brand. Cameroonian medical establishments sometimes import used radiology and echography medical equipment from European suppliers.

## Canada

General Market Condition: Restricted

### *Source:* Report from CS Post (via E-Mail) 2 May 2000

The content of ISA Medical 970901 (*see below*) concerning used/refurbished medical equipment remains fairly current with the following observations and additions:

Although we remain unable to quantify this market, it is fair to assume that demand for used/refurbished medical equipment has grown in Canada over the past three years. It remains minimal in comparison to the total market. It is in the area of refurbishing for existing customers that most market gains would have been achieved in recent years. Surgical endoscopes, both rigid and flexible, is one popular product for refurbishing for existing customers.

Equipment maintenance people in Canadian public hospitals have had to face more budget cuts in the second half of the 1990s. They have learned to use the Internet to access used/refurbished medical equipment businesses on web sites that proliferate and are believed to conduct more sourcing for in-house reconditioning. There is also an occasional demand for used and refurbished equipment destined to backup support, particularly in blood and bio-chemistry laboratories.

Some market gains have been made by private health care businesses in Canada in the past few years, namely in the laboratory, diagnostic, as well as in aesthetic and minor surgery fields. Many of these businesses are strong potential buyers of used/refurbished equipment.

The large demand created by Canada's 950+ network of public hospitals is essentially for new, state-of-the-art medical equipment.

Sources at Health Canada's Medical Device Bureau indicated that used medical equipment refurbished for resale/exports to Canada would be subjected to licensing like new equipment, unless the refurbisher is the original manufacturer that originally obtained licensing for the equipment in Canada. In these cases, the review for licensing clearance would be conducted based only on the specification changes made to the equipment.

### *Source:* ISA Medical 1 September 1997

Although minimal in volume, sales of used/refurbished medical laboratory equipment may be expected to show growth over the next two years in Canada.

#### *Used and refurbished medical laboratory equipment*

Difficult to quantify, sales of used and refurbished medical laboratory equipment in Canada appear to be minimal in relation to total market sales. The purchase of used and refurbished equipment does not fit well with Canada's current public hospital procurement practices. Amortization, manufacturers' warranties, personnel training, and long term servicing arrangements constitute the most important buying criteria. Some used and refurbished equipment may find a place in public hospital laboratories for backup support, provided it can be serviced by the same company that sells and services the newer, more advanced equipment. This seems to be the case for blood and chemistry analyzers. Only U.S.-made used and refurbished instruments appear to be purchased by Canadian hospital laboratories.

Future privatization of healthcare delivery services in Canada could affect the market for used and refurbished medical laboratory equipment, presenting new opportunities. However, no major new legislation in favor of privatization of healthcare in Canada is anticipated in 1997 and 1998. Market conditions are therefore not anticipated to change for at least the next two to three years.

## Chad

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) July 1, 1998

There are no restrictions on the import of used equipment. All imports of used equipment are treated the same as new equipment. There are no exceptions. Chad imports substantial quantities of use and refurbished equipment and goods, including clothing, shoes, ties, used vehicles, heavy equipment, computers, office machines and business equipment, etc. The importation of used equipment is expected to remain an important sector of the economy.

# Chile

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

## *Source:* Report from CS Post (via E-Mail) 9 March 2001

### *Import Regulations For Used Medical Equipment*

#### *Trade Barriers*

Chile generally has few barriers to imports or investment. Foreign firms operating in Chile enjoy the same protection and operate under the same conditions as local firms. The Chilean tariff rate for 2001 is currently eight percent on nearly all products from most countries, although many products from countries with which Chile has trade agreements enter with lower or no duties. Duties on capital goods purchased for use in export production may be deferred for a period of seven years and waived under some circumstances. Imports are subject to the same 18-percent Value Added Tax (VAT) as are domestic goods.

#### *Customs Valuation*

Chilean customs valuation uses the normal value of merchandise, without special discounts, plus freight and insurance (CIF). Used goods are valued by customs according to the current new value of similar merchandise, estimates the actual value of the equipment, based primarily on depreciation tables. The normal 8 percent duty will be applied plus an extra charge for used equipment of 4 percent. All imports are subject to the 18-percent Value Added Tax (VAT).

#### *Pre-Owned (Used and Refurbished Medical Devices)*

There are no restrictions/prohibitions to import used/reconditioned medical equipment/devices into Chile. However, internal regulations of public health institutions and lending banks may require that new equipment be purchased. Large private clinics in Chile prefer to buy new equipment and occasionally will purchase used equipment as long as it does not endanger the life of a patient, i.e. electrical beds, etc.

Health institutions are able to purchase used/refurbished medical equipment with no restrictions. Preference is given to products that come with quality assurance and warranties.

#### *Sanitary Code*

Chile's Ministry of Health amended the Sanitary Code in March of 1997 to authorize the Institute of Public Health (ISP) to regulate medical devices.

These regulations classify medical devices, the same way it is done in the United States by the FDA, with three classes based on risk to the patient. This new system requires that devices have to be tested for quality by a Chilean authorized testing facility and to receive from ISP a Certificate of Quality before they can be sold in Chile. Devices must have an ISP approval seal on their labels.

***Additional Information***

Ministerio de Salud Publica
(Ministry of Public Health)
Instituto de Salud Publica de Chile
Registros—Control Nacional
Marathon 1000
Santiago, Chile
Tel: 56-2-239-1105 extension 640
Fax: 56-2-237-1504
Web Site: www.ispch.cl

Ministerio de Salud Publica
(Ministry of Public Health)
Mac-Iver 541, Piso 2
Santiago, Chile
Contact: Dra. Michelle Bachelet, Minister
Tel: 56-2-639-4001
Web site: www.minsal.cl
E-Mail: info@minsal.cl

Servicio Nacional de Aduanas de Chile
(Customs)
Plaza Sotomayor 60
Valparaiso, Chile
Tel: 56-32-20-0500
Fax: 56-32-23-0591
Web Site: www.aduana.co.cl; www.estado.cl
E-Mail: informac@aduana.cl

Patricia Jaramillo, Commercial Advisor
U.S. Embassy Santiago
Tel: 56-2-330-3402
Fax: 56-2-330-3172
E-Mail: patricia.jaramillo@mail.doc.gov

## China

General Market Condition: Prohibited

### *Source:* Report from CS Post (via E-Mail) 5 February 2002

There is no change to the ban on imports of used medical equipment. There is a new regulation at which we have looked and it does remove some other industrial products from the ban, but not medical equipment, nor many of the other products of interest to U.S. exporters.

### *Source:* Report from CS Post (via E-Mail) 5 April 2001

China still maintains its ban on imports of used medical equipment, the situation has not changed in the past year. However, based on a conversation with an official from the Device Supervision Division of the China State Drug Administration (SDA), there is an intent to draft regulations on imports of such equipment, thus allowing for the lifting of the ban. Unfortunately SDA has no timetable for the drafting of such regulations.

### *Source:* Report from CS Post (via E-Mail) 8 March 2000

Mr. Xianmin Xi, Commercial Assistant, U.S. Foreign Commercial Service, met with Mr. Hao Heping, Director-General of Medical Device Administration of the China State Drug Agency (SDA), the regulatory body for medical devices. He said that they were now working on a regulation on used and refurbished medical products, which have been virtually banned from importation since 1998. Currently, it is still not possible for used and refurbished products to be sold in China.

## *Source:* IMI 5 November 1998

### *Summary*

The January 8 International Business Daily published a notice jointly issued by four ministries and commissions tightening control over the import of used machinery and electric products.

### *Text*

From January 1, 1998, except for special needs with the approval of the State Machinery and Electric Products Import and Export Office, all import of used machinery and electric products are forbidden, regardless of the source of foreign exchange, means of trade, and import channels.

Without approval, units with the right of foreign trade are not allowed to sign contracts or binding agreements for the import of used machinery and electric products.

Foreign exchange administration agencies and banks pay or sell foreign exchange upon presentation of the 'Quota Products Certificate' issued by the State Machinery and Electric Products Import and Export Office, the 'Certificate of Machinery and Electric Products Import,' or the 'Registration Form of Machinery and Electric Products Import.'

The customs office inspects and approves import of used machinery and electric products upon presentation of the 'Certificate of Quota Product,' 'Certificate of Machinery and Electric Product,' 'Import Registration Form of Machinery and Electric Products,' and 'Import Certificate' issued by the State Machinery and Electric Products Import and Export Office and the Ministry of Foreign Trade and Economic Cooperation with a used product note, and the 'Memorandum of the Import of Used Machinery and Electric Product' issued by the State Administration of Import and Export Commodity Inspection.' Violators will be subject to treatment of relevant regulations.

Commodity Inspection Agencies conduct inspections on all the used machinery and electric products approved by the government. The Commodity Inspection Agencies issue 'Notice of Conditions of Import Commodity Inspection' for the used machinery and electric products that conform to the state safety and environmental protection enforced criteria and the inspection criteria as stated in the contract. Unqualified products will be subject to treatment according to relevant regulations of commodity inspection.

Use of import documents for new machinery and electric products to clear used machinery and electric products through customs is strictly forbidden. If discovered, the products will be confiscated by Customs. The customs tariff or other taxes and fees are to be charged based on 60 percent of value of the new product.

### *Comment*

The January 7 *People's Daily*, published the notice in part, and mentioned the following products: used liquid pressure bulldozers, diesel engines for ship use, CT for medical use, and X-ray diagnostic instruments for medical use.

# Colombia

General Market Condition: Restricted

### Colombia : Country Commercial Guide FY 2000

Import Licenses: Colombia has two types of import licenses. The most common is a standard import registration form known locally as 'Registro de Importacion,' which all importers must complete. These forms are for record keeping/statistical purposes and are available at the Colombian Foreign Trade Institute (INCOMEX). The other license applies to closely monitored, sensitive products such as precursor chemicals and weaponry. The majority of 'used' goods, such as personal computers, cars, tires, and clothing, are effectively prohibited from import, and those that are allowed (e.g., used medical equipment) are subje ct to prior licensing.

# Costa Rica

General Market Condition: No Restrictions, but Public Institutions Can Not Buy

### *Source:* Report from CS Post (via Cable) 18 March 2002

The Costa Rican Government does not impose any restrictions on the import of used medical equipment.

There is a strong preference for new medical equipment. Some private clinics and independent doctors occasionally purchase used equipment. Hospitals and clinics within the purlic sector, however, purchase only new equipment, consistent with well established govermment policy.

There is a limited market for used medical equipment in Costa Rica. Used equipment purchased in Costa Rica is usually refurbished by the manufacturer or by an authorized dealer of the manufacturer. It is common for refurbished equipment to carry a minimum six-month guarantee. Used equipment buyers also require assurances that parts and maintenance can be obtained locally.

There are no special restrictions or tariffs that apply to used/refurbished medical equipment. Customs valuation of the equipment is normally taken from the invoice presented by the importer. Costa Rican customs has become concerned about the problem of intentional undervaluation of products being imported into Costa Rica. Exporters and importers can expect special scrutiny of documents for products entering the country that do not reflect reasonable market value.

Used medical equipment imported during past several years includes X-ray equipment, magnetic resonance equipment, electrocardiographs, microscopes, centrifuges, ovens, spectrophotometers, blister packaging for pharmaceutical products, sterilizers, dental chairs with drill systems, and lately, linear accelerators, among other items.

## Croatia

General Market Condition: Restricted

### *Source:* Report from CS Post (via E-Mail) 28 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

No special tariffs exist for importing used or refurbished medical equipment. The import regime is the same as it is for the import of new medical equipment. However, there is a restriction that no imported medical equipment can be older than five years.

*Can public health institutions buy used or refurbished medical devices?*

Public health institutions can buy used or refurbished but never or very rarely do so. They are very sceptical about the quality, guarantees and servicing of used products and they consider it to be a risky business. Therefore, in almost cases, they avoid it.

*Is there a market for used or refurbished medical devices?*

Most medical equipment distributors do not work with used medical equipment because they argue that the market is too small, and that risks connected with this type of business too great. The only customers interested in buying used medical equipment are small private hospitals/enterprises which, faced with limited budgets, are prepared to purchase such equipment. However, even then, the sale of used medical equipment is done, not through distributors or local companies, but through private connections. For example, when they hear about the planned replacement of equipment in a certain hospital in Germany, they buy off the old equipment.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

This small market demand described above includes the most expensive equipment such as X-rays, ultrasound, and electrocardiograph devices.

## Czech Republic

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 4 April 2001 (Information confirmed 25 March 2002)

There are neither special restrictions nor tariffs that apply to used medical equipment and not to new medical equipment. The same procedure applies to the importation of new, used and refurbished medical equipment. To import to the Czech Republic, a foreign producer must have an importer in the Czech Republic. To release a medical device on the Czech market, the manufacturer or importer must arrange for assessment of conformity with essential requirements for medical devices. A manufacturer or importer issues a written declaration of conformity on compliance with technical requirements and abiding by the stipulated conformity assessment procedure. In contrast to the practice applied in the EU countries, where products that have been assessed as to their conformity with the European Council directives bear the CE marking, in the Czech Republic, the declaration of conformity, issued by the producer or importer, is the proof of fulfilling the technical requirements and the conformity assessment procedure. Besides this, the

manufacturer or importer assures distributors of the products in writing that the declaration of conformity has been issued. A medical device must meet medical and technical requirements determined by the manufacturer for the whole period of its use in terms of health care provision.

The Government Orders 180/1998 and 130/1999 stipulate medical devices classification. According to this order, medical devices are divided into the I, IIa, IIb, and III Classes according to their risk. The highest risk devices, including active implantable sanitary medium medical devices, are included in the iii Class. The vast majority of devices are included in the I Class. For placing on the market a medical device from the I Class, the manufacturer or importer makes an assessment of conformity himself. For placing on the market a medical device from the IIa, IIb, and III Classes, the manufacturer or importer must arrange for conformity assessment by an authorized entity. Czech Office for Standardization, Metrology and Testing publishes the list of the entities authorized to assess the conformity in the Bulletin (*Vestnik* ). The Authorized Body assesses the conformity with technical requirements and issues a certificate.

There are no restrictions for public health institutions with regards to purchasing of refurbished medical devices. All health institutions can only purchase medical devices and equipment that are certified by the Czech Ministry of Health for the sale in the Czech Republic.

Czech authorities have no certifying experience with used or refurbished medical devices, as no application for importation of used or refurbished medical devices has been filed yet. However, due to restricted financial sources of healthcare institutions, used or refurbished medical devices may be saleable if price competitive to new medical devices already in the market.

All medical devices imported to the Czech Republic must comply with Czech standards, a warranty must be provided by producer, and service and spare parts must be available during the whole life of the product. Best prospects exist for but are not limited to X-rays, ventilators, operation tables and other price competitive medical devices.

## Denmark

### General Market Condition: No Restrictions, but CE Mark is Required

*See also entry for the European Union.*

### *Source:* Report from CS Post (via E-Mail) 5 March 2001 (Information confirmed 4 March 2002)

Any used medical equipment that does enter the Danish market must carry the CE mark, the obligatory mark allowing the manufacturer/ supplier to circulate their products freely within the European market. In general, there are no specific laws prohibiting the import of used medical equipment other than general ones regarding health, safety and environmental issues. Denmark, as a member of the EU, follows general EU directives.

Public institutions can buy used and refurbished equipment but there is little to no market for used and refurbished medical equipment devices in Denmark.

Although there are no special restrictions or tariffs applicable for used medical equipment that do not apply to new medical equipment, trade associations and industry contacts agree that there is little to no market for used medical equipment in Denmark. From major purchasing authorities (local authorities, etc.) to local distributors, a common consensus exists that only new medical equipment is considered ‘adequate’ for the Danish market.

# Dominican Republic

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 9 May 2000 (Information confirmed 27 March 2002)

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

No, there are no special restrictions for used equipment. Regarding tariff, if the products final use will be in a public/government own hospital, importers may receive import tax exemption. This is usually specified in the purchase contract.

*Can public health institutions buy used or refurbished medical devices?*

Yes, they do. In fact, they prefer to purchase refurbished equipment because of the reduced cost. Public/government hospitals usually by medical equipment through local distributors/importers, therefore, American exporters should contact the distributors/importers instead of the hospitals directly.

*Is there a market for used or refurbished devices?*

Yes, there is a market for both used and refurbished devices, but refurbished have more demand.

*Best Prospects*?

Hospital furniture (specially beds), electro-medical equipment, and diagnosis equipment.

# Ecuador

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

### *Source:* Report from CS Post (via E-Mail) 3 May 2000

There are no restrictions/prohibitions to import used/reconditioned medical equipment/devices into Ecuador. However, internal regulations of public health institutions require that they purchase new equipment. Large private hospitals and clinics in Quito, Guayaquil and Cuenca prefer to buy new equipment and occasionally will purchase used equipment as long as it does endanger the life of the patient, i.e., electrical beds, etc. On the other hand, small private hospitals and clinics in smaller cities favor used/reconditioned medical equipment of all types, but U.S. companies are required to provide a 1 to 5 year guaranty depending on the product. Although private clinics and hospitals will abide to lack of spare parts, provision of same will provide a competitive advantage. Best prospects for used equipment are surgical beds and lamps, electrical beds, X-rays, monitors and sterilizers.

The following companies have been identified as importers/distributors of refurbished equipment:

Advance Biomedical Services / Contact: Jorge Ruiz, Manager
Foch 147 y 12 de Octubre
Quito, Ecuador
Tel & Fax: 011-593-2-238-472
(Importer/distributor of refurbished X-rays, anesthesia equipment, ventilators, respirators)

BIO-IN S.A. Sistemas Medicos / Contact: Boris Toledo A., General Manager
Datiles y 3ra., Local 12
Guayaquil, Ecuador
Tel: 011-593-4-881-569; 881-592; 991-330
Fax: 011-593-4-881-882; 881-331
(Importer/distributor of general medical refurbished equipment, including: X-rays, dialysis, electrical beds, sterilizers, anesthesia equipment)

# Egypt

General Market Condition: Prohibited

### *Source:* Report from CS Post (via E-Mail) 27 March 2002

In January, 2002, Egypt's then-Minister of Health, Ismail Sallam, reiterated a 1991 decree banning the import of used and refurbished medical equipment to Egypt, without a prior approval of the Ministry of Health (MOH).

In the past, Egypt allowed the import of used and refurbished medical equipment. In 1991 the MOH issued Decree #271 banning the importation of used and refurbished medical equipment. The MOH issued this ministerial decree after an increased number of cases where Egyptian companies imported used medical equipment that was proven contaminated, and therefore was confiscated by Egyptian authorities. However, some importers were able to import used medical equipment such as MRIs and X-Ray equipment on an exceptional basis by obtaining prior MOH approval. The MOH approved the importation of such equipment provided that after-sales support and spare parts were readily available.

In January 2002, some foreign companies contacted many University Hospitals offering a wide range of used medical items (including endoscopes, X-ray machines, ultra-sound scanners and renal dialysis equipment) from the U.S. and the U.K. The offers created official concerns regarding the safety of such imports and the fear of unscrupulous business people taking advantage of ill-informed customers in Egypt.

Dr. Fawzy Al Shoura, General Manager for Medical Products Oversight at the MOH, said that the Minister's decree was intended to protect the health of Egyptians, as used medical equipment could be contaminated by infectious diseases. Dr. Mostafa El Hadary, MOH Undersecretary for Drug Policies and Pharmaceutical Affairs, has stated that even new medical equipment should be tested in the country of origin and proven safe before being approved for export to Egypt.

FCS Cairo believes that, as a reminder to importers, the MOH, from time to time, reiterates ministrial decree #271of 1991, which generally prohibits the import of remanufactured and refurbished medical equipment into Egypt without MOH approval.

### *Source:* IMI Medical 29 December 1999, Medical Equipment Import Regulations

The Ministry of Health (MOH) reported, that Egypt would not import any medical equipment except from the country of origin. Dr. Ismail Sallam, Minister of Health, in a press conference, assured that no medical equipment will be admitted into Egypt unless it is imported from the country of origin, and that it must be brand new, not used or refurbished. The importer must submit a form requesting the Ministry of Health's approval to import medical equipment. The

importer will attach to the request a certificate issued by official health authorities in the country of origin, indicating that the medical equipment, subject to importation, is safely used there.

The importer will also present an original certificate from the manufacturer indicating the production year of the equipment and that it is new. In addition, the importer will present a certificate of approval from the Federal Drug Administration (FDA) or a certificate of approval from the European Bureau of Standards. The importer must prove that it has a service center that can provide after sales support for the imported medical equipment, to include spare parts and technical maintenance. The MOH's technical committee will examine and review the technical specifications of the equipment to grant an approval to admit it into Egypt.

### *Source:* Medical Equipment & Supplies in the Egyptian Market: A Guide to American Exporters, 25 February 1999*

On December 16, 1996, Egypt's Minister of Health, Dr. Ismail Sallam, banned the import of used and refurbished medical equipment to stop the spread of diseases. Currently, this restriction remains in effect. The move has sparked a heated internal debate as Egypt has a long tradition of importing used equipment of all types. Egyptian officials defend their action by reiterating that it is intended to protect the population's health. Their concern emanates from a U.S. firm's advertisement offering thousands of used medical instruments and devices at low prices. Officials believe this represents an attempt on behalf of unscrupulous businessmen to dump dangerous products on ill-informed local customers. The negative ramifications associated with any possibility of equipment being introduced with, or becoming contaminated by, infectious disease is a prime concern to health officials.

Some American officials believe the Ministry of Health is merely reconstituting a clause from an older law that banned remanufactured and refurbished medical equipment in 1991. Under this legislation, used equipment can be imported if approval is obtained from the Ministry of Health and acceptable after sales support and spare parts are provided.

* Prepared under contract for the U.S. Department of Commerce, International Trade Administration, Office of Microelectronics, Medical Equipment and Instrumentation.

## El Salvador

No Restrictions (except for Fetal Abortive Products), but Public Institutions Do Not Buy

### *Source:* Report from CS Post (via Cable) 4 April 2000 (Information confirmed 8 March 2001)

#### *Post Review of IMI 5 November 1998 (see below)*

Post reviewed information extracted from the IMI report and found the information on El Salvador is up to date, but would like to complement the report with the following information:

#### *Purchases by Public Hospitals and Clinics*

Post would like to clarify that public hospitals and clinics do not buy used or refurbished equipment as a prevailing practice. It is not a written law or regulation. No change in this practice is expected. The Ministry of Health purchases medical equipment through bids, and although technical terms generally specify new equipment, the Ministry of Health has authorized the purchase of used equipment on occasion. The Ministry of Health also regulates the donation of

used, refurbished, or new medical equipment. These practices do not apply to El Salvador's private hospitals or clinics.

### *Market share*

Medical equipment distributors estimate that the market share for used/refurbished equipment is 20 percent versus 80 percent market share for new equipment. They project that the best prospects for used equipment are in image diagnosis, mainly X-rays and tomographic equipment used to provide mammograms.

### *Prohibited medical products and equipment*

Imports of fetal abortive products continue to be explicitly prohibited by law.

### *Import regulations and tariffs*

Used products are treated the same as new products for the purpose of importation. Used and new medical equipment are free of import tariffs; only a 13 percent value added tax is applied.

### *License requirements*

Currently, no specific license is required to import medical equipment. However, post understands that the GOES' health sector modernization plan will require that every sector (public and private) involved in the supply of medical equipment and health services (clinics, hospitals, distributors, importers, producers, etc.) Must register with the ministry of health, and that only equipment that meets the standards set by the ministry of health will be allowed for importation. The goes expects to implement the plan before 2002.

## *Source:* IMI Medical 8 November 2000

### *Summary*

U.S. companies dominate El Salvador's medical equipment sector. In 1995, U.S. market share reached 72.9 percent, dropped to 66.8 percent in 1997 and rose once again to 79.4 percent in 1999. El Salvador's public and private hospitals and clinics prefer U.S. products due to their price, quality and geographic proximity. The importation of U.S. medical equipment is not restricted and no tariffs are applied for the introduction of medical equipment into the country. The only applicable tax is the 13 percent value added tax.

### *Best sales prospects*

According to our survey, El Salvador is a good market for all types of medical equipment. Government hospitals, hospitals belonging to the Instituto Salvadoreo del Seguro Social (ISSS), hospitals under the military hospital, large private hospitals (40 beds or more), and some clinics are excellent markets for new equipment. While small private hospitals, particularly those outside of san Salvador, provide a good market for new equipment, they prefer refurbished equipment in order to reduce costs. In general, good sales prospects are as follows:

| Harmonized System | Product |
|---|---|
| 9018.13.00 | Magnetic Resonance Imaging Apparatus |
| 9018.19.40 | Equipment for Diagnostic by Images |
| 9018.19.55 | Cardiac Monitors |
| 9018.19.55 | Vital Signal Monitors |
| 9018.90.60 | Equipment for Laparoscopic Surgery |
| 9018.90.60 | Boxes for Abdominal Hysterectomy |
| 9018.90.40 | Pediatric and Adult Biaricular Stethoscopes |
| 9019.10.00 | Respirators |
| 9019.20.00 | Respiratory Ventilators |
| 9022.30.00 | X-Ray Equipment |
| 9026.10.20 | Infusion Pumps |
| 8421.12.00 | Hospital Dryers |
| 8450.11.00 | Hospital Washers |
| 9402.00.00 | Surgery Tables |
| 9402.90.20 | Surgery Beds |
| 9405.10.00 | Ceiling Lamps |

### *Competitive Situation*

There are two basic market types: new equipment and refurbished equipment. The first is the largest, accounting for approximately 80 percent of total sales, and is concentrated in the metropolitan areas of san Salvador, Santa Ana and San Miguel. This market looks more for quality, durability, maintenance and availability of spare parts and accessories rather than price. The refurbished equipment market is concentrated outside of san Salvador and in small hospitals within San Salvador. These institutions generally consider price as the main factor when purchasing equipment. Customers for both of these markets tend to purchase locally and directly although there are a number of small hospitals and clinics that prefer to purchase overseas due to the high cost that local suppliers add to the price of the product.

The key to entering the market is to offer competitive quality, prices and post-sale services. It is also prudent to appoint a local supplier. There is a market for new equipment, as well as for refurbished equipment, which is generally sold to small hospitals. In general, products with favorable sales potential include: ceiling lamps, respiratory ventilators, respirators, equipment for intensive care units, x-ray equipment, equipment for image diagnosis, cardiac monitors, magnetic resonance, equipment for laparoscopic surgery, macro- and micro- infusion pumps, vital sign monitors, boxes for abdominal hysterectomy, pediatric and adult biaricular stethoscopes, surgery tables, surgery beds, and hospital washers and dryers. The products covered by this report correspond to the harmonized system sub-chapters: 901111 to 901210; 901320 to 901820; 901839 to 901920; 902150 to 902290.

The Ministry of Health only purchases new medical equipment; refurbished or used equipment is accepted on a donation basis only. The Ministry of Health purchases medical equipment based on hospital needs. To calculate the hospital's medical equipment needs, doctors and hospital personnel present reports to the Ministry of Health. While it is not necessary to have a local

supplier in order to participate in the medical equipment bids offered by the Ministry of Health, it is highly recommended.

Large, private hospitals prefer to purchase new medical equipment from companies that offer good quality and post-sale services, while small- and medium-sized hospitals purchase new and refurbished medical equipment. Medium and smaller hospitals have observed that local suppliers offer medical equipment products at prices 300 percent over the U.S. price. Approximately 65 percent of small hospitals prefer to purchase their equipment directly from the U.S., and particularly Miami, due to its geographic proximity, competitive prices viz. Local suppliers, importing facilities, and common language.

### *Source:* IMI 5 November 1998

Summary: In general, there are no restrictions on the type, age, or condition of the used/refurbished equipment which can be imported. Used products are treated the same as new products for the purpose of importation. However, while used equipment can enter the country without limitation, regulations within the Ministry of Transportation, Ministry of Health, and other government bodies may inhibit the sale of such equipment by restricting its purchase by governmental bodies or by making it difficult to obtain a license to use such equipment. Import duties in El Salvador for both new and used equipment are described in the Central American tariff system (SAC) and enforced by custom authorities.

El Salvador does not have a comprehensive list of regulated used equipment. Among the items of which import is controlled or prohibited, only fetal abortive products fall within the scope of medical equipment.

Public hospitals and clinics are prohibited from buying or accepting donations of used medical equipment and supplies. This does not apply to the private hospital or clinics.

Industrial sectors of potential growth for used equipment include the following: medical equipment, heavy duty transportation, public transportation (buses), machine tools equipment, construction equipment, used clothing, agro-industrial equipment.

## Ethiopia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 19 June 1998 (Information confirmed 28 March 2001)

There are no restrictions on the import of used equipment in Ethiopia. Importation procedure is the same as for new. The Ethiopian custom authority accepts only factory price.

No categories of equipment are restricted.

The used equipment market in Ethiopia is very good. Due to the shortage of foreign currency in Ethiopia, the private sector especially is more geared towards used equipment. U.S. equipment has a good reputation in Ethiopia for durability and performance, so U.S. firms engaged in used equipment export can take advantage of this growing market.

# European Union

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for individual members states of the European Union.*

## *Source:* Belgium ISA Medical 6 March 2000 (Information confirmed 4 March 2002)

### *European Union (EU) Directives regarding used medical equipment*

The EU Directives have become instrumental in promoting free trade and mutual recognition amongst EU member states.

One piece of legislation promoting uniform requirements for medical devices took effect in January 1995. This legislation (93/42/EC) requires all medical devices, regardless of the proposed use, to carry the CE mark before entering the European market. In order to gain such a mark, a device must pass a regulatory assessment determining whether it is in conformity with EU standards. In addition, the manufacturer is required to make specific information available as to proper and safe use. The Directive requires the manufacturer to specify how a device is to be used, taking into consideration the 'training and knowledge of the potential users.' The appropriate corresponding information for use must be contained in the packaging or labeling of the device. The Directive specifies that the device must be marked 'single use' if that is the manufacturer's intended use of the product. The Directive warns the manufacturer that if the product's 'intended purpose' is not immediately clear to the user, the manufacturer must clearly state it on the packaging, thus re-emphasizing the need for specific labeling so as to avoid misuse. Thus the Directive clearly identifies the liability for product deformity or malfunction as residing with the manufacturer and it outlines the limits of the manufacturer's warranty.

Once a device gains the CE mark, EU law prohibits member states from placing any further restriction on its movement within the EU. Accordingly, once a device has passed the regulatory assessment, the manufacturer's intent for the use of the device has been accepted and deemed appropriate for sale within the EU. This assertion means that the manufacturer's warranty for sale can only extend as far as the first use of the device.

This warranty argument may only apply, however, if the manufacturer has clearly delineated the intended single use in accordance with the Directive. Accordingly, the manufacturer may not specify that the device may be re-used if the manufacturer does not have data illustrating that the device will continue to comply with the Directive upon re-use. Without such data, the device will not receive a CE mark and if the device did enter the market in this fashion, the manufacturer would be in violation of the Directive.

## *Source:* Report from CS Post (via Cable) December 24, 1996 (Information confirmed 4 March 2002)

[This cable reported on discussions with EU official regarding the need for imported used equipment to obtain a CE mark (i.e. are subject to inspection and surveillance). Devices that entered the European Union prior to the CE-mark requirement are grandfathered in and can be resold on the EU market without first obtaining a CE mark. Identical used items can not be imported, however, unless they first receive a CE mark—even if such devices were legally imported into the European Union prior to the adoption of the regulation requiring the CE mark. This rule places importers at a disadvantage compared to European resellers since sale of used equipment within the EU requires no inspection, surveillance or CE mark if such equipment met regulatory requirements at the time of its original sale. The importance of this issue is gradually

fading as medical devices produced before the 1995 introduction of the CE mark reach the end of their useful life.]

## Finland

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via Cable) 6 March 2000 (Information confirmed as still valid, 25 March 2002)

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

No, Finland applies the EU directive on medical devices to both new and used equipment.

*Can public health institutions buy used or refurbished Medical devices?*

Yes, they can.

*Is there a market for used of refurbished devices?*

The market for used of refurbished devices is very small in Finland. The tendency is to buy new equipment directly from equipment manufacturers or distributors. Old or refurbished equipment is sold/exchanged directly between hospitals and other healthcare institutions. In most cases old equipment is donated/sold to Russia and the Baltic states.

*Best prospects?*

Equipment with a long lifetime—imaging equipment, for example.

## France

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via E-Mail) 21 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

No restrictions, but CE mark is required.

*Can public health institutions buy used or refurbished medical devices?*

Yes, but hospitals are reluctant to buy used equipment for liability issues.

*Is there a market for used and refurbished medical devices?*

For the two reasons above, not really, very marginal. Nevertheless, France should still be considered by American companies whishing to export used medical equipment to French-speaking Africa, as some trading companies headquartered in France have extensive distribution networks throughout French speaking Africa.

## Gabon

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) July 6, 1998

Since the devaluation of the CFA Franc in 1994, there has been a significant increase of imports of used equipment, especially cars on the Gabonese market. There are no restrictions on the import of used equipment into Gabon.

## Germany

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* International Marketing Insight, 26 March 2002

[Note: this report is primarily discussing the re-use of single use devices, but see concluding paragraphs regarding the trade fair for used equipment.]

There are no restrictions on the import of used equipment into Germany. New and used equipment fall under the same custom tariff categories (category number: 9018), and the same safety standards apply for both used and new products. In particular, CE marking is required for marketing both new and used medical equipment in Germany.

Traditionally, there has hardly been any market potential for refurbished equipment in Germany because of the existing strict medical product laws and because German buyers have a strong preference for new products. Recently however, and as a result of strong cost-containment pressures following the Health Reform Laws, industrial and commercial customers have positively responded to the refurbishing of medical products. At a conference organized by the German subsidiary of a U.S. provider of refurbished medical equipment, the German medical industry concurred in principle on the advantages of refurbished equipment, provided the highest quality control standards are applied.

There was a consensus that the field of invasive cardiology was particularly suitable for refurbishment. While Class I medical products such as heart catheters and pacemakers, are subject to extremely stringent quality requirements and can only be refurbished by specialist firms in the context of a Quality Management system according to DIN EN ISO 9001 and DIN EN 46001, Class II and III products such as suction tubes and oxygen masks, can be refurbished in hospitals in a fully automated process. The German medical industry, under great cost-containment pressures, has realized that refurbished medical equipment can result in great procurement cost savings. Thus a five-time refurbishment of 2,920 gastro gavage syringes saves a German hospital approx. $ 13,666 on average and reduces the hospital's waste disposal volume by 567 kilograms. Thus, the German market for refurbished equipment is actually growing. U.S. suppliers have to ensure, however, that a specific medical device has been refurbished according to standards outlined in the revised German Medical Products Law ('*Medizinproduktegesetz-MPG*;' 2nd revision in effect as of January 1, 2002) and its respective Medical Products Operations Ordinance ('*Medizinproduktebetreiberverordnung'*). These tighten controls compared to the Medical Products Operations Ordinance of June 1998, in view of consumer protection and the current lobbying of industry associations against the refurbishing of so-called medical 'disposables.' The German government is promoting refurbishing for cost-containment purposes

and has tightened controls, as per the revised ordinance, on some of the loopholes contained in the previous regulations. Revisions include, amongst others:

- A change in definition of 'bringing to market' (cf. Para 3, no. 11 MPG);
- A revised definition of 'refurbishing' in Para 3, no. 14 MPG;
- A regular conformity assessment applying to those who do not return refurbished equipment to the previous user but sell it to third parties (Para 10, section 3 MPG);
- Mandatory registration with the respective authorities (Health Ministry and BfArM) when refurbishing for third parties;
- Inclusion of external service providers in the quality control process (Para 26, section 1 MPG); and
- Amendments to the authorization for refurbishing/maintenance (Para 37; section 5 MPG).

Requirements for the refurbishing of medical products under the Medical Products Operations Ordinance are listed in Para 4, section 2 MPG, mentioning appropriate procedures and the security and health of patients, users, or third parties as top priority. Requirements include:

- Validated Refurbishing.
- Validated Packaging.
- Validated Sterilization Procedures.
- Refurbishing according to the RKI guideline. Recommendations of the Workgroup for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI), Berlin, formed the basis of the revised law. The so-called RKI guideline is available on the institute's website at www.rki.de and has been published in the German Federal Health Register.
- Liability for the health and functional safety of the refurbished products (i.e., the refurbisher takes on the product liability from the manufacturer).
- Quality management system according to DIN EN ISO 9001 and DIN EN 46001.

Refurbished medical products do not need a new CE certification in cases where the user outsources refurbishing and a special documentation safeguards that the refurbished products are returned to the user, i.e., that there is no change in ownership.

Refurbishing of medical products focuses on the following sectors: Electro-physiology; heart surgery; endoscopy; ophthalmic surgery; neurology; urology; heart catheters; digital imaging/angiography; anesthesia; intensive care; general surgery. Excluded from refurbishing are, for example, pressure gauge syringes; spiral lead wires; teflon-coated lead wires; locks and conductors; Olbert-PTA catheters; Wilson-Cook, Endo-Flex and Dispomedica-brand endoscopy balloon catheters; lithotomy baskets; ultrasound catheters, Endo units such as clip applicators; spreaders; Endo shears; plastic implants.

The largest companies in the German refurbished medical equipment market are Remed and Vanguard. Market leader Remed of Friedeburg has approx. 250 customers, mainly hospitals, universities and individual practices, under contract and according to their press spokesperson, expects strong growth over the next few years. Even though currently, roughly 30 percent of the German hospitals refurbish their medical equipment in-house, Remed expects an increase in outsourcing as a less expensive alternative. Remed has refurbished over 250,000 medical

products and over 1,000 different medical product categories over the past years. Remed maintains a website at www.remed.de.

**Table 1: Number of Units Refurbished by Remed**

| | 1997 | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|---|
| **Diagnostic Catheters** | 22,934 | 40,630 | 59,871 | 69,381 | 79,129 |
| **Lead Catheters** | 3,007 | 5,281 | 6,472 | 7,991 | 10,338 |
| **EPU Catheters** | 4,117 | 5,421 | 9,796 | 12,379 | 19,212 |
| **EPU Cables** | 24 | 238 | 2,112 | 3,680 | 8,563 |
| **Rejects** | 7,889 | 13,883 | 32,658 | 30,151 | 49,724 |
| **Total No. of Refurbished Units** | 35,615 | 59,241 | 88,542 | 110,989 | 136,225 |

*Source: Remed*

U.S. subsidiary and Berlin-based Vanguard GmbH Medical Services has successfully refurbished medical equipment in Germany since 1998 and now counts over 100 hospitals as clients. According to their chairman Robert Schroedel, the validated refurbishing can result in substantive economies of scale and savings, estimated at more than 500,000 million Euro annually for all of Europe, several million Euro for large hospitals or university clinics in Germany and 45,000 Euro annually for smaller offices and medical institutions. Vanguard Germany is currently refurbishing over 400 different medical products in validated procedures. See also their website at www.vanguard.de.

Participation in German trade fairs is one of the most cost-effective ways of testing the market's receptivity to a product, investigating competitors and of finding customers or potential agents and distributors. German trade fairs, due to their international significance and large attendance numbers, provide an excellent vehicle for introducing new technologies and products and present a gateway to both the markets of the EU and eastern Europe. Unlike most North American trade shows, the typical German fair is much larger, represents virtually the entire industry, and is a highly successful sales point. German trade shows attract heavy attention from worldwide buyers. The following German trade show is establishing its reputation as the major European trade show for refurbished equipment. It is international in scope, giving visitors, buyers and exhibitors alike the foundation needed to start business relations.

**Name:** *RESALE: International Trade Fair for Used Machinery and Equipment*
**Location:** Nuremberg, Germany
**Dates:** April 22-24, 2002

**Product Groups:** Machinery and equipment for the following industries: Building, Disposal, Energy Engineering, Food Processing, General Industrial, Medical Devices and Equipment, Metalworking, Packaging, Plastics Processing, Printing, Recycling, Textiles, Timber Processing, Utility Vehicles

The show is an annual, trade-only event. For further information on exhibiting or visiting the show, please contact:

Hess GmbH
Rieslingweg 10
76356 Weingarten, Germany
Phone: +49-7244-7075-0
Fax: +49-7244-7075-50
Email: info@resale2002.de
Internet: www.resale2002.de (Please note that interested U.S. suppliers can enter their offers on this English-language website free of charge.)

For specific questions regarding the export of refurbished equipment to Germany or the marketing of refurbished equipment, please contact:

Mrs. Anette Salama
Sr. Commercial Specialist
U.S. Commercial Service Duesseldorf
U.S. Consulate General
Willi-Becker-Allee 10
40227 Dusseldorf, Germany
Phone: +49-211-737-767-60
Fax: +49-211-737-767-67
Email: anette.salama@mail.doc.gov

# Ghana

## General Market Condition: No Restrictions, but Government Health Institutions Are Discouraged from Purchasing

### *Source:* Report from CS Post (via Cable) 2 March 2002

There have been no changes over the past year in import regulations for used medical equipment in Ghana.

Ghana does not have explicit import restrictions or tariffs that apply specifically to used or refurbished medical equipment or used equipment in general. As a matter of policy, government health institutions are discouraged from purchasing this equipment. Apart from assessment of value, customs officials treat all imported equipment in the same way as new equipment.

Used basic medical equipment such as hospital beds, wheelchairs, trollies and furniture, and items that are not high technology are more often purchased by the private sector. Government institutions tend to purchase items that have a higher technology component. Institutions can also accept used or refurbished medical equipment as gifts from donors. One disadvantage of acquiring used or refurbished medical equipment cited by officials is the frequent absence of operation manuals, appropriate training, and spare parts.

The market for used or refurbished medical equipment in both public and private medical institutions is generally limited. Private health institutions, which are increasing in number, present the greatest potential for growth in that market. Because of the lack of local financing resources, interested u.s. firms that can offer some financing in addition to warranty, spare parts, and training to support the equipment can best take advantage of this opportunity.

The major types of used or refurbished medical equipment in greatest demand include scanners, hospital beds, wheel chairs and furniture, ultra sound, sterilizers, X-ray equipment, and laboratory equipment, such as autoclaves.

## Greece

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via Cable) 2 March 2002

In general, Greece does not apply any restrictions on imports of used equipment and machinery, provided it has the CE mark and complies with European Union safety and operations regulations. More specifically, regulations for used medical equipment are governed by EU regulations: 90/385 EEC, 93/42 EEC, 98/79 EC. No special restrictions or tariffs apply to used medical equipment that does not apply to new medical devices.

Despite the absence of restrictions on the purchase of used medical equipment, there does not appear to be much demand for such equipment in the Greek market.

However, some private health institutions, medical laboratories, and small to medium-sized clinics are purchasing used or refurbished dental equipment, scanning devices, ultra-sound and analytical equipment. Such purchases appear infrequent and isolated.

## Guatemala

General Market Condition: No Restrictions

### *Source:* ISA Medical 1 September 1997

Approximately 20 percent of medical equipment imported into Guatemala is used or reconditioned equipment. This equipment consists of, but is not limited to, portable X-ray machines, ultrasound equipment, anesthesia equipment, operating tables, and surgical equipment. About 90 percent is bought directly in the United States by physicians opening small hospitals. Clinics and small health care facilities known as '*sanatorios*' usually purchase their equipment from large Guatemalan hospitals or from a small group of firms that refurbish the equipment and offer some sort of short-term guarantee. *Sanatorios* are usually very small hospitals established by one doctor or a small group of doctors who often do not have the financial resources to purchase new equipment. One distributor expressed interest in representing a well-established U.S. company that offers used medical equipment so that local consumers can have guarantees and after sales service. The potential for used medical equipment with local representation is very good.

Private hospitals are divided into the following categories:

- Relatively expensive, well established hospitals offering modern equipment, nice installations, and specialized medical staff;
- *Sanatorios*, which are small, privately owned hospitals that do not offer the latest installations, equipment, or medical staff, but do offer more accessible rates; and
- Day hospitals where patients stay for only a few hours after a surgical or other procedure. Many of the large hospitals now have a day hospital.

Private entities buy significant quantities of disposable medical products but their needs are much lower than those of the public sector. The larger hospitals have more resources and are able to purchase modern equipment from local distributors. *Sanatorios* and the like usually purchase used medical equipment.

Most firms selling into the Guatemalan market do so by means of a Guatemalan agent or distributor. However, used equipment dealers tend to sell directly to Guatemalan buyers. Generally speaking, the more pre-sales marketing and after-sales support and service that a product requires, the more important it is to have a local agent or distributor.

## Guinea

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

### *Source:* Report from CS Post (via Cable) 5 May 2000

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

In Guinea, there are no special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment. The importation of used medical equipment is authorized by the Government of Guinea (GOG).

*Can public health institutions buy used or refurbished medical devices?*

Public health institutions do not buy used or refurbished medical devices. The GOG provides these health institutions with new medical equipment. It is GOG policy not to buy used equipment.

*Is there a market for used or refurbished devices?*

The market for used or refurbished devices is very small. Private clinics or hospitals are free to purchase used or refurbished equipment but most of them have very limited resources.

*Best Prospects*?

Private clinics or hospitals are the best prospects since public health institutions depend on the Government for medical devices.

## Haiti

General Market Condition: No Restrictions

### *Source:* International Market Insight, *Regulatory Requirements & Market Prospects For Used Medical Equipment*, 12 March 2002

#### *Regulatory Agency*

The Haitian Ministry of Public Health and Population supervises the healthcare sector for the country.

#### *Regulations*

There are no regulations for the enforcement of quality, technical or safety standards. The Haitian Government does not restrict the importation of used/refurbished medical equipment.

#### *Standards*

Both U.S. and European standards are currently accepted and respected by the purchasing entities

### *Import Duties and Taxes*

Used medical items entering the Haitian customs territory are subject to the same import tax treatment as new items. Import duties on medical devices are 16 percent. The tariff system is on a CIF basis. The value of imported goods, either FOB or CIF, is converted into Haitian gourdes at the prevailing daily rate, prior to the application of duties and taxes.

### *Distribution*

The market prospects for imports of all types of used/refurbished medical equipment is relatively strong, since new medical equipment is considered to be expensive, U.S. companies have a number of options for entering the Haitian market place, including direct exporting, franchising, licensing, and wholesaling. The most common method involves the use of an official representative or distributor, as the Haitian commercial code does not allow foreigners to engage in wholesale or retail business without first obtaining a professional license. Most foreign firms are represented by agents in Port-au-Prince, who then distribute products to the provinces. The commercial code is designed to protect Haitian citizens who work as agents and distributors for foreign companies. The Haitian tax code includes a withholding tax provision, which, in practical terms, discriminates against foreign investors. Foreign companies are subject to an additional levy of 30 percent on profits as a final tax on deemed distributions to foreign shareholders, whereas local firms are subject to only a 15 percent withholding tax on distributions. The government has committed itself to removing this disincentive to invesment; however, further administrative action is required to implement this commitment.

### *Contact List for Medical Equipment and Health Services Exporters*

Ministry of Public Health and Population
Palais des Ministeres
Rue Monseigneur Guilloux
Port-au-Prince, Haiti
Dr. Henry-Claude Voltaire, Minister
Ph: (509) 222-2728/222-7020
Fax: (509) 223-6248

Division D'hygiene Publique
Direction Centrale de Pharmacie et de Controle
Des Substances Chimiques
59 Rue des Miracles
Port-au-Prince, Haiti
Mr. Eric Dubosse, Director
Ph: (509) 223-6826

Association Medicale Haitienne (AMH)
24 Rue Capois
Tel: 509) 2238334
Fax: (509) 223 9885
Email: amh@haitiworld.com

Hopital de l'Universite d'Etat
Rue Monseigneur Guilloux
Centre Ville
Port-au-Prince
Telephone: (509) 222 1066/222 4344/223 4261

Hopital Francais
Rue du Centre
Port-au-Prince
Haiti
Telephone: (509) 222 5966/223 9979/223 9988

Hopital St. Francois de Salles
Angle Rue Chareron et Rue de l'Enterrement
Port-au-Prince
Haiti
Telephone: (509) 222 5033/222 71 32/222 0232

Hopital du Canape Vert
Route du Canapé Vert
Port-au-Prince
Haiti
Telephone: (509) 245 0984/245 0985/245 6105
Fax: 245 0985

Association Medicale Haitienne (AMH)
24 Rue Capois
Tel: 509) 223 8334
Fax: (509) 223 9885
Email: amh@haitiworld.com

### *Source:* Report from CS Post (via Cable) 10 April 2000

In general, the Haitian government does not restrict the importation of used/refurbished equipment other than through two regulations, one governing the imports of used clothing, furniture, bedding, and shoes, the second governing the importation of used cars (limited to one used car per person per year). These two regulations are not enforced and these items are freely imported into Haiti.

All used items, entering the Haitian customs territory are subject to the same import tax treatment as new items. However. Only one category of items, used cars pay an additional ten percent (10 percent) CIF. Tourist tax which does not apply to new cars. Medical equipment, whether new or used, enter the territory duty free but, like any imported item, are subject to other import taxes: 4 percent CIF Verification fee, 2 percent CIF. For community management, 2 percent CIF. Account tax, 10 percent value added tax (VAT) on ex-customs value.

Public health institutions as well as private health institutions are allowed to and in fact import used or refurbished medical devices therefore indicating the existence of a market for used or refurbished devices.

## Honduras

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

### *Source:* Report from CS Post (via E-Mail) 27 March 2002

According to the Honduran Customs and Tax Division, there are no restrictions or quotas for the importation of remanufactured, rebuilt, and/or used medical equipment to Honduras. The import tariff for used medical equipment is the same as that for new equipment. The appraisal for

remanufactured, rebuilt, and/or used medical equipment is carried out at any port of entry in the country by the customs agent. The import tax paid for such products is 1 percent of its CIF price.

At present, public health institutions are only allowed to purchase new medical equipment and supplies through public and international bids. According to the Ministry of Public Health, the only used medical equipment acquired has been donated. However, since it is more expensive to acquire new medical equipment, the Government of Honduras is planning to modify the current regulation in order to allow the purchase of used or refurbished equipment (as long as it is accompanied by a warranty of at least 6 months).

According to industry representatives, there is a good market for used and refurbished medical equipment, especially if after-sales support, repair parts, and warranty options are available. Approximately 10 percent of medical equipment imported into Honduras is used or re-conditioned.

Among the best prospects for used medical equipment are X-ray and monitoring equipment, hospital beds, sterilizing equipment, and surgery and intensive-care equipment.

For additional information on the market for used and refurbished medical equipment in Honduras, please contact Elizabeth Danforth at the Commercial Service Office in Tegucigalpa, Honduras, tel. (504) 238-5114, fax (504) 238-2888.

## Hong Kong

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 13 March 2002

In Hong Kong, there are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment. Hong Kong agents and distributors in this industry prefer to source the 'newest and latest' equipment. There is limited market for used and refurbished medical equipment. Public hospitals, private hospitals and health institutes in Hong Kong do not buy used medical devices. There is very little business opportunity for used/refurbished medical equipment in China due to government restrictions.

## Hungary

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 26 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment?*

No, there are no special restrictions/tariffs that apply to used medical equipment, that apply to new medical equipment.

*Can public health institutions buy used or refurbished medical devise?*

Yes, public health institutions can buy used medical devices.

*Is there a market for used or refurbished medical devices?*

The market is very limited for used/refurbished medical devices. Most of the healthcare institutions are state-owned and 'are not interested in saving on equipment purchases.' Right now clinics prefer to wait until they have enough money for a new device instead of 'saving on time and money' by purchasing used or refurbished equipment. There has not been a tradition of buying used equipment in Hungary and people seem reluctant to buy pre-owned devices. Hungarians do not consider purchasing refurbished medical equipment as a real option.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

There are only ad-hoc purchases of pre-owned equipment.

### *Source:* Industry Sector Analysis, Medical Equipment, 15 February 2002

Leasing of medical equipment has no tradition in Hungary and is in its very early stages. The market for used/refurbished medical equipment has also been very limited in Hungary. However, with increasing privatization opportunities, their sales prospects might improve.

### *Source:* Report from CS Post (via E-Mail) 26 March 2001

In Hungary the use of used/refurbished medical equipment is rather limited. The reason might be the regulation below, or simply little tradition so far.

In response to an inquire with the Authority for Medical Devices in the Hungarian Ministry of Health, he Deputy Director advised as follows: 'there are no special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment. Public Health institutions can buy used/refurbished medical devices. The general rule, that applies to all medical equipment and devices (whether imported or locally manufactured) is a Ministry Decree of 1998 (21/1998/VI.3), Annex 17. This annex lists all medical equipment/devices with the 'approved / authorized length of life,' it actually tells/prescribes to all medical institutions how long they can use their equipment. In practice, as the Hungarian health care system lacks funding, the Ministry does not 'check' how old the equipment are, as the government-owned hospitals/clinics could hardly afford to buy new equipment. However if a clinic would want to buy a piece of used equipment, the Authority for Medical Devices would register/check how old the equipment to-be-imported is, and would tell the clinic for how many more years it could use the equipment.'

## Iceland

General Market Condition: No Restrictions, but CE Mark is Required

### *Source:* Report from CS Post (via E-Mail) 4 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

No, there are no special restrictions or tariffs that apply to used medical equipment. The same rule applies to both new and used medical equipment. However, as in most European countries, Iceland requires the CE mark on all medical equipment, used or new.

*Can public health institutions buy used or refurbished medical devices?*

Yes, they are allowed to buy used or refurbished medical equipment but so far no interest has been shown to do so, simply because health institutions prefer to purchase new equipment.

*Is there a market for used or refurbished medical devices?*

According to the Icelandic Ministry of Health there has not been a market for used or refurbished medical equipment, since institutions prefer to purchase new equipment.

*If there is a market, what types of used or refurbished medical equipment are in greatest demand?*

Not applicable.

# India

General Market Condition: Restricted

## *Source:* Industry Sector Analysis, *Cancer Diagnostic and Treatment Equipment*, 28 April 2001

End-users are becoming increasingly aware of the state-of-the-art Cancer Diagnostic and Treatment Equipment (CD&TE) equipment available in the world market. Most of India's leading cancer specialists attend medical conferences in the United States and Europe to keep abreast of the latest technologies. Price, product features and payment terms are key factors which influence purchase decisions of hospital administrators. Charitable organizations and rural hospitals unable to afford the latest, new equipment often purchase used or reconditioned equipment imported from abroad.

Used medical equipment also has market potential in the country. The present GOI's current Export-Import policy allows imports of used equipment including used CD&TE equipment. Used equipment including CD&TE equipment that is less than 10 years old can be imported into the country. The importer should not sell, transfer or otherwise dispose of this equipment within a period of two years from the date of import. The Director General of Foreign Trade, New Delhi, will grant a waiver to this requirement. Price-sensitive Indian end-users prefer to buy refurbished medical equipment including cancer treatment equipment for some low-end applications. However, these buyers look forward to continued support for spare parts and service commitments.

## *Source:* Report from U.S. Commercial Service, November 2000

In July 2000, India's Directorate General of Foreign Trade (DGFT), Ministry of Commerce, issued a policy circular detailing guidelines for importing second-hand capital goods, including medical equipment. The policy incorporates changes to paragraph 5.3 of the Export Import Policy of 1997-2002 and paragraphs 5.29 and 5.30 of the handbook of procedures. As per the provisions contained therein, import of second-hand capital goods is restricted and subject to import licensing procedures.

Applications for such licenses are considered by the inter-ministerial Restricted Items Licensing Committee under the DGFT, New Delhi. The Committee will consider such applications according to the following guidelines:

- Capital goods not older than 5 years: The committee will normally allow imports of such capital goods automatically.
- Capital goods older than five years but less than ten years old: The committee will take into consideration the comparative advantages/benefits of such imports vis-à-vis new capital goods.

- Capital goods older than 10 years: Imports of such capital goods normally will not be allowed except for heavy equipment in the infrastructure and core sectors.

The imported capital goods will have to conform to acceptable environmental and industrial safety norms. Apart from the criteria mentioned above, the committee might establish any other criteria, as it may deem necessary.

## *Source:* IMI 9 December 1999

Under immense pressure from the domestic industry the Indian Government has eased the imports of second-hand machinery. The Government of India will now allow second hand capital goods imported into the country under the special import license route. An importer has to purchase the special import license from the open market at a premium and can import the second hand machinery, which is less than five-years-old. For machinery more than five-years-old the current procedure for imports will apply. It will not be possible for importing capital goods more than ten years old. A notification to this effect is being prepared by the Indian government.

Ministry officials said applications for import of second-hand machinery more than five years old will be placed before special licensing committees in the same manner as application for import of other restricted items.

When the new export import policy was announced in March 1999, several industry associations had complained that import of used equipment must be made easier so that the Indian industry can acquire the latest equipment and compete globally. This new announcement is in keeping with the demand from the user industry and the chamber of commerce representations.

Capital goods account for 25 percent of total imports and 75-80 percent of the capital goods imported into India was used machinery and equipment. Such a large percentage of imports will now be able to bring in latest equipment. This will also facilitate the import of used equipment by small-scale sector, which can not afford new capital equipment.

## *Source:* ISA Medical 31 March 1999

### *Best Prospects*

Refurbished medical laboratory instruments also find a ready market in India. These instruments are used as back-up machines in top-of-the-line hospitals. Less sophisticated hospitals and district hospitals view refurbished medical laboratory instruments as optimal for their laboratories because the investment cost is substantially lower than for new instruments. Some international companies operating in India also sell used medical laboratory instrument to their Indian customers. Also, Indian hospitals and agents demand continuous service support for these instruments and require spares when needed. U.S. Companies in the used/refurbished medical instruments business may consider setting up liaison offices in India to promote their products.

## *Source:* IMI 16 July 1998

There are several restrictions on the import of used equipment in India, prescribed by India's import-export policy, in force from 1997 to 2002. Second-hand capital goods with a minimum residual life of 5 years can be imported by actual users of such equipment without a license. The importer is required to furnish a self-declaration to the customs department specifying the residual life of the second-hand capital goods in a prescribed format.

The importer is also required to furnish a certificate from an internationally reputed inspection and certification agency that the purchase price of the equipment is reasonable. This certificate is required at the time of clearing the goods through customs, where the CIF value of the goods exceeds Indian

rupees 10 million (US$ 238,000). Where the second-hand equipment has a CIF value of up to RS. 1 million (US$ 23,800), customs authorities will not insist upon such a certificate.

The second hand equipment shall not be transferred, sold or otherwise disposed of within a period of 5 years from the date of import, except with prior permission of the director general of Foreign Trade. While selling, U.S. firms should remember that valuation of used or second-hand equipment is a very technical area with frequent disputes between customs and the importer. For problems, U.S. exporters can contact:

Mr. L.N. Lakhan Pal, Director General of Foreign Trade
Ministry of Commerce Government of India
Udyog Bhavan, Maulana Azad Road
New Delhi 110001, India
Tel: 91-11-301-1777 Fax:91-11-301-1779

Spares, including accessories and tools for the maintenance and operation of such equipment, can be imported to the extent of 15 percent of the value of the equipment.

India is a high-cost economy for capital equipment, and Indian manufacturers and investors constantly seek to reduce their capital costs. For this reason, demand for used and reconditioned equipment is high across a range of industry sectors. The best opportunities for U.S. firms to pursue are in the industry sectors of construction, mining, medical, machine tools, plastics, steel, oil refining, computers, printing, packaging and dairy equipment.

While rates of customs duty vary from product to product, they are, generally speaking, lower for used equipment as compared with new equipment.

# Indonesia

## General Market Condition: No Restrictions, but Public Institutions Can Not Purchase

### *Source:* IMI Medical 18 February 2000

The Ministry of Health prohibits public hospitals from using used or refurbished medical equipment, however, this prohibition does not apply to private hospitals. Given the poor economic condition in Indonesia, the purchase of new medical equipment is no longer affordable for most hospitals. The situation has compelled private hospitals to seek alternative medical products at an affordable price.

Indonesian medical suppliers discovered that since 1999, the request for used/refurbished medical equipment has increased. This is because hospitals need to replace the old equipment, which was mostly purchased before the economic crisis. According to the medical suppliers, the purchases for used/refurbished equipment are still very low, however, they anticipate the demand will gradually increase in the future.

To protect their image, medical equipment suppliers refused to sell both new and used equipment, although they would do it on a case by case basis upon order. Hospitals were unwilling to buy used/refurbished medical equipment because they claimed that they did not get good service from the manufacturer, spare parts were hard to replace, and after sales service was poor. To take the greatest advantage of export opportunities, used/refurbished equipment suppliers should be able to provide training, technical assistance, spare parts, and after sales service.

The import tariff for medical equipment for both used and new ranges from 5 to 10 percent with a value-added tax of 10 percent.

### *Source:* Report from CS Post (via Cable) 22 February 2000

The Ministry of Health (MOH) prohibits public hospitals from using used or refurbished medical equipment but there is no written regulation on this.

Private hospitals are not bound to the above policy. Imports of used or refurbished equipment had not been very significant in the past. Because of low purchasing power, private hospitals are beginning to show interest in used or refurbished medical equipment.

Local medical suppliers anticipate that the demand for used or refurbished medical equipment will gradually increase in the future.

The import tariff for both used and new medical equipment ranges from 5 to 10 percent. It is subject to a value-added tax (VAT) of 10 Percent.

## Israel and Palestinian Authority

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 4 April 2000 (Information confirmed and contact names added 22 February 2002)

The Israeli and the Palestinian Authority (PA) markets for used medical devices are very small and considered insignificant for U.S. exports. There is a limited market in the PA for high-cost devices such as X-ray machines, CT scans, and MRI units. However, used devices that require expensive maintenance because they are old, are not desired.

There are no special restrictions or tariffs that apply to used medical devices imported to Israel and the PA. All imports of used devices are treated the same as new, and Israeli and PA hospitals and clinics may import used and refurbished devices.

Public health institutions in Israel must register their medical devices with the Israel Ministry of Health (IMOH). Registration is applied to new, as well as used equipment. Registration with the IMOH provides a legal protection to the institution, in case of malfunction of the device. Many private institutions in Israel prefer to pass the IMOH registration process and to enjoy the legal liability.

In order to register any medical device, IMOH requires an FDA or equivalent approvals, and a declaration from the U.S. manufacturer, or from the local agent, that a complete maintenance service is guarantied for the device. If the device is used, or refurbished, IMOH requires the complete history of the device: who used it and for how long, what type of maintenance or refurbishment it had passed, etc.

For more information, contact:

*Israel:*

Yael Torres, Commercial Specialist
U.S. Commercial Service, Tel Aviv
Tel: 972-3-5197611
Fax: 972-3-5107215
E-mail: ytorres@mail.doc.gov

*The Palestinian Authority:*

Issa Noursi, Commercial Specialist
U.S. Commercial Service, Jerusalem
Tel: 972-2-6255201
Fax: 972-2-6235132
E-mail: inoursi@mail.doc.gov

# Italy

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via E-Mail) 22 march 2002

There are no restrictions or special tariffs on imports of used and refurbished medical equipment into Italy. However, the CE mark is required for all used or refurbished medical equipment and devices, and the same safety standards apply for new and used alike.

Though there are no impediments to the purchase of used and refurbished medical equipment, but the prevailing practice in public hospitals and medical facilities is to purchase new equipment because of liability issues. Public hospitals are forced to comply with current regulatory issues, which mandate that all equipment and devices utilized in public healthcare facilities has to be in accordance with CE mark regulations, in effect from June 1998, by Directive 93/42/EC. The public healthcare service accounts for over 75 percent of expenditures for medical equipment.

The Italian market for used medical equipment is very small and is mostly confined to the private sector. The majority of used medical equipment now available has been on the market prior to the directive, and in most cases does not have the CE Mark, nor does it meet the stringent safety parameters. The process of refurbishing medical equipment to the point of meeting the requirements of the directives and to acquire the CE Mark is very costly and, once completed, makes the selling price of pre-owned equipment prohibitively expensive. Consequently, savings are not enough to justify the purchase of used equipment. To be appealing, the price of used and refurbished medical equipment should be approximately 40 percent less than the selling price of new equipment. Sales of refurbished medical equipment must be supported by pre- and post-sale marketing and technical assistance.

A niche market exists for used and refurbished medical equipment that can be sold to small, privately owned healthcare facilities— which due to their size and specialization are exempted from fully complying with the existing regulations—and to private practitioners. Thus, the best selling used medical products are diagnostic imaging equipment, EKG, monitoring equipment, ultrasonic equipment, ophthalmology equipment, dental chairs and dental equipment, and apparatus and equipment for physical therapy and rehabilitation.

# Jamaica

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 3 May 2000

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

> None of which the Post is aware, but all imported equipment should ideally be approved by the Jamaica Bureau of Standards.

*Can public health institutions buy used or refurbished medical devices?*

> Yes, but again subject to the conditions above. All of last year, Y2K was a big thing. Health services were announcing that they would only be buying items that were Y2K compliant.

*Is there a market for used or refurbished devices?*

In theory there should be, but new items are greatly preferred.

*Best prospects?*

Unknown.

# Japan

General Market Condition: Restricted

## *Source:* Report from CS Post (via E-Mail) 26 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment?*

All imports of used equipment are treated the same as new, and thus each product must obtain MHW (Ministry of Health and Welfare) approval for import.

Although there is no tariffs levied on medical devices, this area is highly regulated by the Pharmaceutical Affairs Law of the Ministry of Health, Labor and Welfare (MHLW). In order to market a foreign medical product in Japan, an importer must obtain "manufacturing approval" (*shonin*) for safety and efficacy of a medical product. In order to handle a shonin-approved product, an importer or a seller needs to obtain "*kyoka*" license based on its facility, personnel and qualification of a technical director. A foreign manufacture may obtain the *shonin* approval by using an in-country care taker (ICC). If a foreign manufacturer receives a *shonin* approval, an importer is not required to obtain a shonin approval for such items.

In many cases, a Japanese importer receives "manufacturing approval" (*shonin*). It means that an importer who has a *shonin* approval will have a full control. If a different importer wishes to sell the same product (either used or new), this importer must receive a product approval from the Ministry. If a U.S. manufacturer holds an approval, they can sell their product through multiple distributors that have "*kyoka*" license to sell medical devices in Japan. A Japanese doctor can import a medical device to treat his/her patients at his/her risk. However, in this case, no reimbursement is given for those treatments, and thus direct import from Japanese general clinics and hospitals is very limited. Japanese beauty clinicians and veterinarians often import new and used medical device as their treatments have no reimbursement coverage in Japan's system.

*Can public health institutions buy used or refurbished medical devise?*

Although there is no statistical information available, used/refurbished medical equipment is becoming more attractive to medical institutions, including public hospitals, because of cost factors. This trend may continue coming years as the financial status of many Japanese hospitals is also becoming more precarious. Over 70 percent of Japanese hospitals are believed to be operating in deficit and the number of hospitals declaring bankruptcy is increasing. More efficient use of used/refurbished medical equipment may be needed to meet these growing financial challenges.

*Is there a market for used or refurbished medical devices?*

The sale of such equipment in Japan is a more viable option for local manufacturers and re-sellers than for third-party exporters. Industry sources indicated that market demand for such equipment is particularly strong for ultrasonic diagnostic equipment, X-ray equipment, clinical examination/laboratory equipment, etc.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

The Japan Federation of Medical Devices Associations (JFMDA) has prepared a guide on the handling of second-hand medical devices with the objective of establishing a closer network system between manufacturers and medical facilities and to ensure the safer and more effective use of these devices.

## Jordan

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 28 June 1998

Equipment is assessed the tariff that applies to its Harmonized Tariff Schedule (HTS) category, regardless of whether it is new or used. The base value of used equipment, however, is depreciated according to the judgment of the customs inspector. Therefore, the net customs levy on used equipment may be lower or even higher than on new equipment, depending on the customs inspector.

No customs duties apply to new or used industrial equipment if it used for production.

## Kazakhstan

General Market Condition: No Restrictions

### *Source:* IMI 26 August 1998

Kazakhstan does not have any special regulations for the importation of used/refurbished equipment. This type of equipment can be imported in accordance with regular customs import requirements. Licenses and certificates of conformity may be required for the import of certain types of equipment.

Kazakhstani customs does not distinguish between new and used equipment when being declared for customs clearance. Used equipment is released subject to completion of the customs clearance process which is same as for new equipment. There are no special duties for the importation of used equipment in Kazakhstan.

Licenses are required to import equipment that may affect the health of citizens, the environment, or national security. These types of equipment are subject to mandatory safety certification.

The best industry sectors for the export of certain types of used/refurbished equipment to Kazakhstan are: automotive, oil and gas, power generation, medical, agriculture, and food processing. Subject to the availability of warranties and spare parts, cheap used medical, agricultural, and food processing equipment is believed to have better marketability versus expensive new equipment.

# Korea, South

General Market Condition: Restricted

## *Source:* Report from CS Post (via E-Mail) 29 March 2002

### *Summary*

There is a small, but growing demand in Korea for used/refurbished medical products, particularly for the latest models of internationally recognized premium brands of radiography equipment. Market demand is strongest for used computer tomography(CT), magnetic resonance imaging (MRI) equipment, X-ray mammography equipment, and premium quality ultrasound scanners. Although the Korean government implemented major regulatory changes to open the market for imports of used/refurbished medical equipment in 1997, such imports are still encumbered by requirements for extensive technical information and U.S. FDA certificates for local pre-market approvals. Thus, the sale of such equipment in Korea is more of a viable option for manufacturers than for third-party exporters. Under current regulations, the realization of this growing market potential is heavily dependent on the ability of U.S. exporters to provide such information for their Korean distributors to obtain necessary approvals.

### *Market overview*

Prior to July 1997, the Korean government prohibited the importation of used/refurbished medical equipment. Since the ban was lifted through regulatory changes, the market demand has grown significantly and primarily for expensive radiography equipment. A growing demand has emerged for a few types of used capital goods for medical institutions, including Computer Tomography (CT) equipment, magnetic resonance imaging (MRI) equipment, mammography X-ray equipment, premium quality ultrasound scanners, and diagnostic biochemical analyzers. There is also a strong demand for laser printers used for diagnostic X-ray imaging equipment. In particular, local end-users are mostly interested in recent models of internationally renowned premium brands that would otherwise very expensive, if purchased new. In terms of numbers of units, the strongest market demand has been for blood analyzers, diagnostic X-ray equipment and ct equipment. The market demand for diagnostic blood analyzers increased from 19 units in 1998 to 84 units in 1999 but dipped to 63 units in 2000. The demand for computer tomography equipment steadily increased from 45 units in 1998 to 103 units in 1999 to 114 in 2000. In 1998, 15 units of diagnostic X-ray equipment were sold in Korea; that number increased to 44 units in 2000.

Commercial Service (CS) Korea will update the table below on import statistics after the Korean Government publishes its 2001 statistics in April 2002. Import statistics from 1998 to 2000 for some of the used/refurbished medical equipment that have been in greatest demand are listed below.

**Import Statisics for Selected Categories of Used/Refurbished Medical Equipment 1998–20000**

| | 1998 | 1999 | 2000 |
|---|---|---|---|
| Diagnostic X-Ray | 15 units | 14 units | 44 units |
| CT | 45 units | 103 units | 114 units |
| MRI | 4 units | 12 units | 13 units |
| Diagnostic Blood Analyzer | 19 units | 84 units | 63 units |
| Surgical Laser | — | 11 units | 14 units |

According to local industry sources, imports of used medical equipment in 2001, including Computer Tomography (CT) and Magnetic resonance Imaging (MRI), decreased for the first time since 1997. Below are unofficial import statistics from Korea Test Laboratories (KTL) for major categories of used medical equipment. KTL is an independent medical device testing facility approved by the ROKG.

**Import Statistics of Major Used Medical Equipment**

| | 1997 | 1998 | 1999 | 2000 | 2001 | Total |
|---|---|---|---|---|---|---|
| CT | 21 units | 38 units | 101 units | 114 units | 41 units | 315 units |
| MRI | — | 2 units | 12 units | 9 units | 5 units | 28 units |
| Mammography X-Ray | — | — | — | — | 22 units | 22 units |
| Surgical Laser | — | — | 7 units | 11 units | 17 units | 35 units |
| Others | 6 units | 5 units | 14 units | 35 units | 59 units | 119 units |
| Total | 27 units | 45 units | 134 units | 169 units | 144 units | 519 units |

*Source: Korea Test Laboratories*

Despite Koreans' strong disposition against used products in general, the market demand initially emerged in the midst of the country's economic crisis, which erupted in late 1997. Although Korea is recovering from the overall economic crisis, a new crisis, the near bankruptcy of the national healthcare system, has begun to put severe cost-containment pressure on the market demand for all types of medical equipment. Additionally, the dramatic depreciation of the Korean won has precluded many health institutions' ability to purchase expensive, imported equipment in the price range of a few hundred thousand dollars to a million dollars. All of these factors are causing Korean hospitals to seek alternatives to the latest models of highly expensive equipment and to opt for used/refurbished equipment that incorporates the best technologies at considerably reduced prices.

### *Major players*

The major players active in the re-marketing sector of used/refurbished medical equipment are the same as those active in marketing new products of the same brands. For example, large multinational radiography equipment suppliers, such as General Electric, Toshiba and Hitachi and Philips have all begun to implement re-marketing programs for their proprietary brands. Foreign manufacturers re-market used/refurbished products either through their Korean subsidiaries or through their Korean distributors. Imports of used/refurbished equipment sourced from third-party re-marketers are very few in number, primarily as a result of regulatory requirements for

product approvals and the advantage that manufacturers' distributors enjoy in terms of product knowledge and after-sales service.

### *Future prospects and competitive elements*

There is a strong consensus among industry experts that the market demand for used equipment will continue to increase over the next several years. With Korea's healthcare system experiencing a financial crisis, the pressure for cost-containment is expected to remain high, and local healthcare institutions will continue to seek inexpensive alternatives for capital medical equipment.

Although competitive pricing is a critical competitive factor, Korean health care institutions are also very concerned about the quality of used/refurbished equipment. They expect to be offered comprehensive warranties and to work with a trustworthy, technically qualified distributor who can provide competent after-sales service.

The full realization of this high market potential, however, will have to rely heavily on the ability of foreign exporters to provide together extensive technical information and U.S. FDA certificates for pre-market approvals, as described below.

### *Regulatory Environment*

There are no special restrictions or tariffs that apply to used medical equipment that do not also apply to new medical equipment. Just as new products are subject to pre-market approvals, so are imports of used/refurbished equipment. Since an approval for a product is granted to a locally-based firm, the full process of review for approval must be repeated for the same product each time a different local firm imports the product.

The Korean regulatory agency, Korea Food & Drug administration (KDFA), requires an equal amount and degree of product information for approvals for both new and used products. In practice, each used/refurbished piece of equipment is treated as a separate, re-manufactured product. As part of the process, the importer of used/refurbished equipment must submit a certificate to foreign government (CFG), which is issued by the U.S. FDA, as well as extensive technical information on the product. Most Korean distributors are aware from their experiences in working with U.S. third-party exporters that the CFG is usually available only from the U.S. manufacturer. Therefore, it is very difficult for the Korean importer who does not have a direct business relationship with the U.S. manufacturer to provide the necessary documents for approval. As a result, Korean importers of used/refurbished equipment are either local subsidiaries of the manufacturers or authorized distributors for new products of the same brands.

Korean regulations mandate additional testing requirements for used medical devices. Each piece of used/refurbished equipment must be tested by a KDFA-authorized lab not only as part of the pre-market approval process but also throughout the post-approval marketing period. (In contrast, newly manufactured equipment is required for testing by a authorized-authorized lab only for pre-market approvals.) Nonetheless, Korean importers do not view this approval process as a major import barrier since testing is normally straightforward and fees are reasonable.

In order to encourage small hospitals to share expensive equipment, regulations require hospitals to receive prior approval from the Ministry of Health and Welfare (MHW) for purchases of equipment costing over US$ 500,000. Under the present system, only hospitals that specialize in radiology, have 200 beds or more, and have on-staff at least one physician specializing in diagnostic radiology can own MRI equipment. General hospitals must have 70 beds or more in their own facilities with an additional 130 beds or more in other facilities in order to share an MRI.

***Used/refurbished equipment purchases by public institutions***

There are no special regulations prohibiting public hospitals from purchasing pre-owned equipment. However, public hospitals do not appear to consider purchasing used/refurbished equipment as a viable option since as non-profit organizations, there is no internal incentive to control operational costs. Another factor is the long cycle involved in obtaining budget appropriation approvals from funding authorities. Since the availability of supply of used/refurbished equipment is not known far in advance, public hospitals prefer to work with predictable cost factors and, therefore, to purchase new equipment, regardless of cost.

## Kuwait

General Market Condition: Prohibited

### *Source:* Report from CS Post (via Cable) 29 April 2002

Kuwait's public health institutions do not buy used/refurbished medial devices. All tenders call for new devices and equipment. The public health sector represents about 90 percent of the total market, with the remaining 10 percent for the private sector. The latter does not buy used devices. Tariffs are imposed on new equipment only (currently at 4 percent of value); it will be increased to 5 percent in 2003. Used equipment will not be permitted to be imported. Used/refurbished equipment does not have a market in Kuwait.

### *Source:* Report from CS Post (via Cable) 19 October 1998 (Information confirmed 18 March 2001)

The export market for used equipment in Kuwait is extremely limited. As a policy, the Government of Kuwait will not purchase used equipment for use in any of its ministries or para-statal companies. Since these two categories account for approximately 90 percent of the economy, the limited potential is readily apparent.

In addition, outright prohibitions exist in Kuwait against the importation of the following:

- Used medical equipment and instruments.
- Used vehicles manufactured prior to five years from the date of importation.
- Used clothes and other items of personal wear.

## Kyrgyzstan

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 7 August 1998

The Kyrgyz Republic has the following regulations for importation of used/refurbished equipment:

A. Currently, there are no restrictions on the imports of used equipment to Kyrgyzstan. All equipment, whether used or new, imported into the country is treated the same way;

B. However, if a company intends to import used/refurbished equipment, it is strongly recommended to specify this in agreements and other documents;

C. According to Kyrgyzstani experts, the used/refurbished equipment can be used almost in all industries, first of all in such branches as electric power, electro-technical, light and food industries as well as agriculture. Unfortunately, the National Statistical Committee does not track the market for the equipment in question.

# Liberia

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via Cable) 2 March 2002

### *Overview*

Liberia does not have restrictions on the importation of used or refurbished medical equipment. There are no specific laws that govern the importation of used or refurbished medical equipment. Neither government nor private health institutions are discouraged from importing or purchasing used medical equipment. However, the Ministry of Health must certify drugs and other medical expendibles that are imported into the country.

Used medical equipment is not treated or handled differently from new equipment with regards to custom and tariffs.

Most of the medical equipment used in Liberia at the moment is not of high technology. According to sources at the Ministry of Health in Monrovia, most medical equipment used in government hospitals is used or refurbished, donated by NGOs from the United States and Taiwan.

Private health institutions are the biggest importers and users of used and refurbished medical equipment and statistics indicate that they will remain so for the next couple of years, as most government health institutions remain closed or in derelict state.

The major types of used or refurbished medical equipment in greatest demand in both public and private health institutions include laboratory equipment, hospital beds and furniture, X-ray equipment, scanners, surgical equipment, cardiac monitors and printers, baby incubators, pediatric weight scales, iv poles, transfusion pumps, and phaco-emulsifier machines.

### *Responses to Specific Questions*

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

There are no special restrictions or tariffs that apply to used or new medical equipment. Neither used nor new medical equipment have special restrictions or tariffs that favor one over the other.

*Can public health institutions buy used or refurbished medical devices?*

Yes, public health institutions can buy used or refurbished medical devices.

*Is there a market for used or refurbished devices?*

Yes. As a matter of fact, used or refurbished medical equipment are imported or bought more often than new ones, primarily because of economic reasons.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

Used or refurbished medical equipment in greatest demand include laboratory equipment, hospital beds and furniture, x-ray, scanners, surgical equipment, cardiac monitors and printers, baby incubators, pediatric weight scale, i.v poles and transfusion pumps and phaco-emulsifier machines.

***Sources***

Mrs. Sodey Lake, Administrator, Tubman National Institute of Medical Arts (Tnima)
Amelia Ayomanor Nursing Administrator, John F. Kennedy Medical Center
Ministry of Health, Information Section
Ndu L.Adighibe, Assistant Minister of Commerce for Foreign Trade

## Malawi

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 15 October 1998

Malawi has no policy, regulations, or restrictions on the importation of used equipment, according to a representative of Malawi's Ministry of Commerce and Industry.

[This cable does not specifically address used medical equipment.]

## Malaysia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 29 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

Medical devices and appliances have no import duty. No duty is imposed on used medical devices or equipment.

*Can public health institutions buy used or refurbished medical devices?*

Government hospitals do not ban used or refurbished medical devices. Howerver, due to safety reasons and after-sale service issues, they prefer to buy new medical devices. Moreover, it is not common for medical products distributors to sell used medical devices to public hospitals.

*Is there a market for used pr refurbished medical devices?*

The market is very small, almost negligible.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

Not applicable.

### *Source:* Industry Sector Analysis, *Healthcare Sector Overview*, 26 September 2001

Nearly all medical equipment, instruments and supplies are imported, and the main exporters are the U.S. followed by Japan, Germany and Australia. All medical products are not dutiable. While most imported medical equipment is now more expensive due to the depreciation of the local currency, many are still reluctant to use refurbished medical equipment due to its safety concerns. Moreover, the level of health care services still needs to be upgraded to satisfy the demands of an increasingly affluent and health-conscious population. The Government of Malaysia has still not imposed regulations on medical devices yet. It was mentioned that the Medical Device Act is in its final stage and that it will be implemented soon. However, certain high-tech medical equipment, such as x-ray equipment, equipment that uses lasers and others, are subject to stringent pre-purchase evaluation by the Ministry of Health's Health Technology Assessment Unit.

## Mexico

No Restrictions when Imported by End-User; Restricted when Imported for Resale; Public Institutions Can Not Purchase

### *Source:* International Market Insight, Refurbished Medical Equipment Show 2002—Mexico City, 19 March 2002

In October 1999, the U.S. Commercial Service, Mexico City (USCS) launched the first show in Mexico for refurbished medical equipment. The show was a complete success. All exhibiting companies had floor sales or obtained serious leads. The USCS organized the show again in October 2000.

In the year 2001, the U.S. Commercial Service turned over the recruitment and mounting of this event to REMEX, a leading Mexican private show organizer, who will repeat the event annually. The next *Equipo Medico Reconstruido* (Refurbished Medical Equipment) show will be in October 22-24, 2002, in the new and modern exhibition hall at the Hipodromo de las Americas, in Mexico City.

This show, initiated by the U.S. Department of Commerce, U.S. Commercial Service, Mexico City is now in its fourth edition. In 1999 the show had 15 exhibitors. In the year 2000, the show increased 46 percent to reach 22 exhibitors. The 2000 show attracted 875 visitors and reported floor sales of U.S. $331,300. In addition to the 22 exhibitors, the show had the support of a specialized health care products customs broker, a publisher of medical directories, and the Mexican Association of Biomedical Engineers. Parallel to the show, technical seminars were organized to inform the visitors on the advantages of purchasing good refurbished medical equipment, selection criteria, and importance of proper maintenance.

After staging these two successful events, the 2001 show was expected to reach 50 exhibitors and increase significantly the floor sales. Unfortunately, due to the September 11 events, many companies canceled their participation and the show had only nine exhibitors.

Now that the business environment is recovering its normal rhythm, the 2002 show is expected to attract many more exhibitors. The show will again include: parallel seminars,the participation of key medical associations, the Mexican secretariat of health, and a number of Mexican companies that offer technical support to imported equipment. This year, the number of exhibitors is expected to reach 50 companies and 2000 visitors are expected to visit the event.

The Mexican market for imported medical equipment surpassed the US $ 500 million in the year 2001. It is estimated that at least 10 percent of these imports corresponded to refurbished medical equipment.

Best prospects are refurbished medical equipment and devices that can be offered with warranty and technical support in Mexico.

This show will offer U.S. companies the opportunity to:

- Exhibit equipment or catalogs directly to decision makers
- Participate in seminars to explain characteristics of their equipment and services
- Meet personally with the purchasing managers of medium and small hospitals in Mexico
- - Contact Mexican companies that are currently providing technical support to Mexican hospitals

*Equipo Medico Reconstruido 2002* is an excellent opportunity to promote products to a qualified audience of hospital owners, administrators, biomedical engineers and private doctors that look for quality equipment and devices offered at reasonable prices.

The cost to participate in *Equipo Medico Reconstruido 2002* for a 9 square meter furnished booth is $ 30,208.00 Mexican pesos (US $3,248 at the current exchange rate), and $47,610.00 pesos (US $5,120 at the current exchange rate) for a 18 square meters unfurnished booth. The current exchange rate is 9.30 Mexican pesos per US dollar.

Those American companies wishing to participate in *Equipo Medico Reconstruido 2002* should contact,

In the United States:

Ms. Lana Stokes
Tel: (512) 267-9035
E-mail: lstokes@swbell.net

In Mexico:

Lic. Angel Martinez Torres
General Manager, Medical Area
REMEX
Av. Rio Churubusco esq. Anil s/n
Palacio de los Deportes, Puerta 1
Col. Granjas Mexico
08400 Mexico, D.F.
MEXICO
Tel: (011-52-55) 5237-9949, 5237-9986, 5237-9989
Fax: (01152-55) 5657-5926

## *Source:* Industry Sector Analysis, Medical Equipment, 29 September 2001

Private clinics and sanatoriums usually purchase used equipment sold by large public or private hospitals. They also buy domestically refurbished equipment or refurbished equipment imported from the U.S. Few clinics and sanatoriums have budgets for purchasing new equipment.

Medium size private hospitals may purchase new or refurbished equipment depending on budget. Private medical centers mainly look for state-of-the-art equipment. They like to get financial support from manufacturers or distributors, when possible.

All private health care units select suppliers by requesting price quotations. Their decisions are based on the best equipment at the best price.

## *Source:* Report from CS Post (via E-Mail) 17 April 2000

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

Same as specified in ISA 1 February 1998 (*see below*). Requirements have not changed.

*Can public health institutions buy used or refurbished medical devices?*

No. Public institutions are not allowed to purchase used or refurbished medical equipment in Mexico.

*Is there a market for used or refurbished devices?*

Yes. Most small and medium hospitals in Mexico lack of enough resources to purchase new equipment. To optimize the use of funds, they look for refurbished equipment that is in good operating conditions and have technical support available.

*Best prospects?*

All kinds of medical equipment, instruments and accessories have good potential in the Mexican market. Please see IMI 27 September 1999 (*see below*).

## *Source:* IMI Medical 10 December 1999

### *Summary*

On October 19-21, 1999, the U.S. Commercial Service, Mexico City, held the first show in Mexico for refurbished medical equipment. The show was a complete success. All companies participating had immediate sales or obtained serious sale leads. The show will be repeated annually. Next show will be held on October 17-19, 2000.

### *Body*

On October 19-21, 1999, the U.S. Commercial Service, Mexico City, held the first show and seminar series in Mexico for refurbished medical equipment. In this show, 15 American companies exhibited a wide variety of medical equipment and accessories. Also as exhibitors were a custom broker, a publisher, an American trade association, and a Mexican professional association. In the seminars, several exhibitors explained the advantages of good refurbished medical equipment. The Mexican association of biomedical engineering presented the Mexican end users point of view and requirements, and a FDA officer presented the FDA policies on this matter.

During the three days of exhibition, there were 972 qualified visitors, including hospital and clinic managers, private doctors, and distributors of medical products.

Floor sales reached us $95,000.00 and potential sales for the next 12 months are estimated in $2.2 million. Each exhibiting company obtained an average of 50 sales leads as well as several potential agents or representatives in Mexico.

After the successful 1999 event, the U.S. Commercial Service, Mexico City has decided to annually organize an event for refurbished medical equipment. The next will be held in October 17-19, 2000.

The October 2000 event will again include parallel seminars. Plans include to increase the number of exhibitors and add the participation of medical associations in Mexico.

This show will offer American companies the opportunity to:

- Exhibit equipment or catalogs directly to the decision makers;
- Participate in seminars to explain characteristics and benefits of their equipment and services;
- Meet personally with the purchasing managers of medium and small hospitals in Mexico willing to discuss their products and services; and
- Contact Mexican companies that are currently providing technical support to Mexican hospitals and that are available to be their technical counterpart in Mexico.

Best prospects include:

- All kind of equipment for gynecology
- Anesthesia equipment
- C-arms
- Developing apparatus for x-ray plates
- Electrosurgery equipment
- Fluoroscopic equipmenty
- Hemodialysis machines
- Hydraulic and ambulance stretchers
- Incubators
- Laparoscopy equipment
- Magnetic resonance
- Radiant incubators
- Surgery instruments
- Surgery tables
- Ultrasounds
- Vital signs monitors
- X-rays
- All kind of equipment for urology
- Bronchoscopes
- Defibrillators
- Duodenoscopes
- Endoscopy flexible apparatus
- Gastroscopes
- Hospitals beds and furniture
- Imaging equipment
- Intensive therapy equipment
- Lithotriptors
- Patient monitors
- Sterilizers
- Surgery lamps
- Transport incubators
- Urethroscopes
- Volume and pressure ventilators

### *Commercial Implications For U.S. Firms*

The Mexican market for refurbished medical equipment has proven to be an excellent niche for American companies that offer good quality products with technical support and warranty.

## *Source:* IMI Medical 27 September 1999

### *Summary*

The Mexican market for refurbished medical equipment represents an unexploited niche for American companies. Due to the economic conditions, only large and medium private hospitals can afford purchasing new equipment. Almost 85 percent private hospitals in Mexico are currently purchasing or looking to purchase refurbished medical equipment and devices.

***Body***

Mexico has 2,945 private medical facilities. 0nly 3.2 percent or 95 units are large hospitals having more than 50 beds. The remaining 96.8 percent or 2,850 medical units are small clinics and hospitals having from 5 to 49 beds.

The small and medium medical units do not have the financial resources to buy new equipment. The preferred way they have to increase their equipment inventory or to substitute obsolete equipment, is through the acquisition of refurbished medical equipment that is in good conditions and has availability of service and spare parts in Mexico.

Most of the 2,850 small and medium hospitals are already importing refurbished equipment from the United States or are willing to do so.

If each of these hospitals invest at least US$ 10,000 a year in refurbished equipment, there is a potential minimum market of US$ 28.5 million.

There are also 105,000 Mexican doctors with private offices. They like to have their own small or portable equipment for better attention to their patients, such as ultrasound, X-ray, imaging equipment, microscopes, sterilizers, etc. If each of these doctors invest at least US$ 500 a year in refurbished equipment and devices, the potential market would be of US$ 75 million.

The key to this market is to offer equipment that is in good operational conditions, at a good price and offering technical support in Mexico.

Best prospects include:

- All kind of equipment for gynecology
- Anesthesia equipment
- C-arms
- Developing apparatus for x-ray plates
- Electrosurgery equipment
- Fluoroscopic equipment
- Hemodialysis machines
- Hydraulic and ambulance stretchers
- Incubators
- Laparoscopy equipment
- Magnetic resonance
- Radiant incubators
- Surgery instruments
- Surgery tables
- Ultrasounds
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- All kind of equipment for urology
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- Hospitals beds and furniture
- Imaging equipment
- Intensive therapy equipment
- Lithotriptors
- Patient monitors
- Sterilizers
- Surgery lamps
- Transport incubators
- Urethroscopes
- Volume and pressure ventilators

## *Source:* ISA Medical 1 February 1998

### *Refurbished Medical Equipment*

This report focuses on used and refurbished medical equipment purchased by small and medium private sector users. Distribution channels are developing, as many end-users purchase directly from foreign sources. This is an emerging and a so far unexploited market that offers very good opportunities for U.S. exporters of such equipment.

Because of the market dependence upon imported equipment and a lack of economic resources, small and medium private clinics have for decades bought used medical equipment from large public and private hospitals. Public health care institutions do not buy used or refurbished medical equipment.

The high cost of medicine is also driving private doctors to install portable or small equipment in order to provide simple laboratory tests, analysis and outpatient surgery, and so help patients to avoid hospital expenses.

The main distribution channel is through those medical equipment repair firms serving specific clients. Most pieces of refurbished medical equipment are purchased and imported directly by end- users. Statistical information on the value of the imports is not available. This equipment is included either as imports of new equipment, or as scrap or products of limited value.

Some Mexican repair companies provide advice to their customers on the purchasing and importing of used or refurbished medical equipment. However, very few repair companies import directly for resale or to maintain an inventory. Mexican Government Sanitary and Customs import requirements are difficult to comply with and costly to implement. This situation does not leave the Mexican repair firms with a reasonable profit margin.

The Mexican market for refurbished medical equipment is estimated at US$ 14 million for 1997. Ninety percent of this market is supplied by imports from the U.S. This market could grow at an annual average of 10-15 percent in the coming years if foreign suppliers offer warranties and service in Mexico. Providing financial support to end-users would also prove a very successful marketing strategy.

Best prospects include equipment for: anesthesia, hospital waste management and treatment, intensive care, laparoscopy, patient monitoring, radiotherapy, respiratory therapy, sterilization, tomography, ultrasound diagnosis, and X-ray.

While public health care institutions and large private hospitals are augmenting and modernizing facilities and equipment, they do not purchase used or refurbished equipment. However, small and medium size private hospitals do buy refurbished equipment and are improving their facilities to provide more and better services.

#### *Best Prospects*

Best sales opportunities for refurbished medical equipment include:

- Anesthesia
- Defibrillators
- Laboratory
- Incubators
- Intensive care
- Tomographers
- Respiratory therapy
- Sterilization
- Ventilators
- Ultrasound diagnosis
- Diagnostic imaging
- Patient monitoring
- X-rays
- Home care

The market for this equipment can increase if products are offered with a warranty and a service provision. Offering financial assistance will provide an excellent tool to develop the market. Those U.S. companies who do not have a representative in Mexico could try signing contracts with those Mexican companies offering medical equipment repair service in order to offer technical support to buyers of used and refurbished medical equipment. The best competitive factor to successfully penetrate the Mexican market for used and refurbished medical equipment would be offering credit to end-users. Many small private hospitals and private doctors are willing to buy equipment but lack the immediate financial capacity to do so.

Another important competitive factor is after sale service, including training and spare parts availability. Of course, quality or properly operating equipment is just as important.

Domestic production consists of imported used medical equipment used sold by large Mexican public and private hospitals and refurbished by Mexican companies for specific clients or for sale to others. This refurbishing activity is very limited. Most used equipment sold by large health care institutions is scrap, as it is usually in poor operating condition. Some refurbishing firms cannibalize equipment—taking parts for several units to complete one unit.

Some private hospitals buy used equipment from U.S. companies but hire a Mexican company to refurbish the units. Very few Mexican firms import used equipment for refurbishing and resale. The investment is too high to be profitable.

The United States is the only foreign supplier of used and refurbished medical equipment in the Mexican market. Some private hospitals and doctors that imported refurbished equipment from Europe and Asia in past years found the process of obtaining technical support or even parts for the equipment very frustrating. End users of used and refurbished medical equipment prefer suppliers with geographical proximity.

There is no official information on imports of used and refurbished medical equipment. However, it is estimated that in 1997 these imports reached US$ 12.9 million. Most of these imports were made directly by the end users.

End users of refurbished medical equipment are small and medium private hospitals and private doctors who prefer to have small or portable equipment in their offices. Public health care institutions currently do not purchase used or refurbished medical equipment.

The recent Mexican economic crisis resulted in many small private hospitals not being able to replace obsolete equipment and acquire new units. Clinics and *sanatorios* have traditionally purchased the equipment discarded by large public and private hospitals. They also buy equipment that has been refurbished in Mexico or have directly imported refurbished equipment from the United States. Some private hospitals purchase used equipment, from domestic or U.S. sources, and hire a company to refurbish it. These clients always seek to save money while obtaining the best equipment. Very few clinics and *sanatorios* have budgets for purchasing new medical equipment.

Medium size private hospitals may purchase new or refurbished units depending on available budget, the condition of the equipment and its capabilities. However, they often will not buy refurbished units because they do not trust the condition of the equipment or a warranty or technical support is not provided.

Private medical centers [a 50+ bed hospital] do not buy refurbished equipment. They prefer state of the art units.

To be imported to Mexico, used and refurbished medical equipment and accessories have to meet legal, technical and tax requirements. These include applying for import permits with the

Secretariat of Health and complying with regulations on labeling, quality standards, certificate of origin, duties and providing after sales services to clients.

***Importation of Used Or Refurbished Medical Equipment For Resale***

The Secretariat of Health specifies that only Mexican companies registered as medical products distributors may import used or refurbished medical equipment for resell. To be authorized, Mexican companies must comply with the following requirements:

1. Be legally established, registered and authorized as medical product distributor. Authorization from the Secretariat of health is required.
2. Designate a responsible person. This person must be a biochemical engineer or the like, with the professional background and ability to verify the equipment condition, according to specific tests.
3. Maintain a registration log that is approved by the Secretariat of Health. This log must contain all information concerning the importation of the equipment, including:
    - Name of the apparatus
    - Importation sanitary permit number
    - Operation tests applied
    - Invoice number
    - Warranty and services provided to end user
    - Brand name
    - Date of import
    - Name of importer
    - Sale or lease date
4. Present a document proving the sterilization system used, if applicable.
5. Present the equipment invoice specifying that the equipment is used or refurbished and that it is in operating condition. If the equipment or the apparatus is to be dismantled to obtain parts, it must be so specified in the invoice.
6. Offer warranty and technical services to customers.
7. Present the FDA export certification.
8. Comply with the Mexican standards for specific equipment such as X-rays, infrared rays, etc.

***Importation Of Used Or Refurbished Medical Equipment By The End User.***

When the used or refurbished medical equipment is imported into Mexico by the end user (hospital, private doctor), there are no barriers. The only requirement is to obtain an import permit from the Secretariat of Health and present the invoice specifying that the product is imported, specifying if the equipment is used or refurbished and that it is for private use and not for resale.

As there are no third persons involved, the importer is responsible for the operation and use of the equipment. The importer will also need to request directly from the supplier, a warranty or the technical support, if offered by the seller.

***Equipment Registration With The Secretariat Of Health***

Used and refurbished medical equipment does not need to be registered with the Mexican Secretariat of Health.

***Labeling For Imports***

On January 16, 1997, the Mexican Official Gazette published for comments, NOM-137-SSA1-1995, which will regulate the labeling of health care products, diagnostic agents and medical

equipment whether domestically manufactured or imported, including used and refurbished equipment. This NOM is still in the process of being approved.

According to this standard, the label should contain:

1. Product name (trademark or commercial name brand of the product).
2. Name or business name and address of the manufacturer.
3. Name or business name and address of the importer.
4. Country of origin.
5. Sanitary registration number or letter specifying that registration is not required.
6. Expiration date or date of recommended consumption or use.
7. Lot or serial number.
8. Net contents (as specified in NOM-030-SCFI-1993).
9. Warnings or precautions on hazardous products.
10. Use, handling, and care instructions, when they are not obvious. If required, instructions must be attached. In these cases the label must specify-See attached instructions.
11. According to the consumers' law, the medical equipment label or instructions must specify the location of the repairs, and include instructions or manual and warranty.
12. For sterile products specify-sterility will not be granted if the original package is broken.
13. Legend specifying that the product is free of toxins or pyroxenes, when applicable.
14. Specification for disposable products, when applicable. Information required in points 3, 5, 9, 10, 11, 12, 13 and 14 may be attached to the products after the importation custom process, but before selling the product to the public. For bulk products, information is only required in the bulk container.

These requirements do not apply to:

1. Highly specialized medical equipment.
2. Medical equipment to be used in commercial, industrial or service areas.
3. Medical equipment imported by persons or institutions for their own use.
4. Medical equipment imported by educational or scientific institutions.
5. Samples of health care products or diagnostic agents imported to be used exclusively for the certification process to comply with Mexican standards.
6. Other medical equipment that because of size or nature cannot bear a label, or when the label size is not adequate to contain the information required. In such cases the Secretariat of Health will determine the course of action.
7. Other medical equipment, health care products or diagnostic agents determined by the Secretariat of Health.

This information must be on products prepared for retail sale. Listing this information on the container in which a product is packed for shipment will not satisfy the labeling requirement. The above-mentioned requirements also comply with the labeling standard NOM-050-SCFI.

There are few Mexican standards for medical equipment and accessories, but various agencies are preparing more standards to be issued in the near future. As of January 1998, Official Standards for medical equipment are:

- NOM-001-SCFI-1993 for ultraviolet & infrared ray apparatus published in the Official Gazette, October 13, 1993.
- NOM-003-SCFI-1993 for electric massage apparatus, published in the Official Gazette, October 13, 1993.
- NOM-157-SSA1-1996, for protection and security measures for the use of diagnostic X-ray equipment, published in the Official Gazette, September 29, 1997.
- NOM-158-SSA1-1996, for technical specifications for X-ray medical equipment, published in the Official Gazette, October 20, 1997.

The December 28, 1995 decree provides a list of products by Mexican tariff number, which are subject to NOMs. A clarification and update of this list was published on June 28, 1996, but that list is not all-inclusive. All NOMs apply the same for new and used or refurbished pieces.

For information on the NOM certification process, please consult the Industry Sub-sector Analysis (ISA) on the Process of Standardization and Certification in Mexico, by Jesus Gonzalez, September 1996, and available on the National Trade Data Bank.

***Certificate of Origin***

The basic Mexican import document is the *pedimiento de importación.* A commercial invoice must accompany this document (in Spanish), a bill of lading, and documents demonstrating guarantee of payment of additional duties for undervalued goods (see 'Customs Valuation') if applicable, and documents demonstrating compliance with Mexican product safety and performance regulations (see 'Standards'), if applicable. The import documentation should either be prepared or submitted by a licensed Mexican customs broker, or by a person with customs experience.

Products qualifying as North American must use the NAFTA Certificate of Origin in order to receive preferential treatment. This may be issued by the exporter or broker and does not have to be validated or formalized. Certificate of Origin information is available on the NAFTA Facts in documents 5000-5003 at telephone number (202) 482-4464. The Certificate of Origin may be issued by government agencies, producers, exporters, or industrial and commercial chambers of commerce or associations that are legally authorized in the U.S. or other countries.

Mexican customs law is very strict regarding proper submission and preparation of customs documentation. Errors in paperwork can result in fines and even confiscation of merchandise as contraband.

***Import Fees***

Used or refurbished medical equipment pays the same import duties as new units. The following 52 products, classified under the harmonized system, are listed. Under NAFTA, starting in January 1998, 50 of these codes are duty free for American products, against 10 to 20 percent ad-valorem duty for third country products. (*See table below.*)

**Mexico Tariff Schedule**

| Harmonized Numbers Schedule | Current Import Duties Other/USA | Product | NAFTA Tariff Reductions |
|---|---|---|---|
| 9011.1001 | 10/0 | Microscopes for surgery | B |
| 9011.1099 | 20/0 | Other microscopes | B |
| 9011.2099 | 20/0 | Microscopes for Micro projection | B |
| 9011.8099 | 20/0 | Other microscopes | B |
| 9011.9001 | 10/0 | Microscope accessories | B |
| 9012.1001 | 10/0 | Diffraction apparatus | A |
| 9012.9001 | 10/0 | Accessories for diffraction apparatus | A |
| 9013.2001 | 10/0 | Lasers, other than laser Diode | A |
| 9018.1101 | 10/0 | Electrocardiographs | A |
| 9018.1201 | 15/0 | Ultrasound diagnostic apparatus | A |
| 9018.1301 | 10/0 | Magnetic resonance imaging Apparatu s | A |
| 9018.1401 | 10/0 | Nuclear medicine diagnostic Apparatus | A |
| 9018.1901 | 10/0 | Tonometers & retinoscopes | A |
| 9018.1902 | 10/0 | Electro-encephalographers | A |
| 9018.1904 | 10/0 | Diathermy apparatus, short-wave | A |
| 9018.1905 | 15/0 | Patient monitoring equipment | A |
| 9018.1906 | 0/0 | Audiometers | FREE |
| 9018.1907 | 10/0 | Cardioscope | A |
| 9018.1908 | 10/0 | Gamma ray apparatus | A |
| 9018.1909 | 15/0 | Incubators | A |
| 9018.1910 | 10/0 | Electro-surgical apparatus | A |
| 9018.1911 | 10/0 | Dermatomere | A |
| 9018.1912 | 10/0 | Defibrillator & surgical appliances | A |
| 9018.1913 | 10/0 | Electro-ejaculators | A |
| 9018.1999 | 10/0 | Other medical apparatus | A |
| 9018.2001 | 10/0 | Ultraviolet & infrared ray apparatus | A |
| 9018.9004 | 15/0 | Anesthetic apparatus | A |
| 9018.9005 | 15/0 | Equipment for cephalorachidian liquid control | B |
| 9018.9014 | 10/0 | Pleural suction pumps | B |
| 9018.9015 | 20/0 | Suction apparatus | A |
| 9018.9020 | 10/0 | Actinotherapy apparatus | A |
| 9018.9022 | 10/0 | Accessories for anesthetic apparatus | A |
| 9018.9025 | 10/0 | Electronic detectors of Pregnancy | B |
| 9018.9026 | 10/0 | Modular circuits for Electronic detectors of Pregnancy | B |
| 9019.1001 | 10/0 | Hydrotherapy & mechano-therapy appliances | A |
| 9019.1002 | 15/0 | Massage apparatus | A |
| 9019.1003 | 10/0 | Accessories for therapy appliances | A |
| 9019.1099 | 10/0 | Other therapy apparatus & accessories | A |
| 9019.2001 | 10/0 | Respiration therapy apparatus | A |
| 9021.1904 | 10/0 | Appliances for fracture treatment | A |
| 9021.2199 | 10/0 | Other accessories | A |

| Harmonized Numbers Schedule | Current Import Duties Other/USA | Product | NAFTA Tariff Reductions |
|---|---|---|---|
| 9021.5001 | 10/0 | Pacemakers for stimulating heart muscles | A |
| 9021.9099 | 10/0 | Other orthopedic appliances | A |
| 9022.1201 | 10/6 | Tomography equipment | C |
| 9022.1401 | 10/0 | X-ray equipment | A |
| 9022.1499 | 10/0 | Other radiation equipment | A |
| 9022.2101 | 10/0 | Cobalt pumps | A |
| 9022.2199 | 10/6 | Other radiation apparatus | C |
| 9022.2901 | 10/0 | Calibrators beta | A |
| 9022.3001 | 10/0 | X-ray tubes | A |
| 9022.9003 | 10/0 | Accessories for X-ray apparatus | A |
| 9022.9099 | 10/0 | Other parts or accessories for X-ray apparatus | A |

A: Full duty elimination occurred on January 1, 1994.

B: Full duty elimination occurred on January 1, 1998.

C: Duties shall be removed in 10 equal stages of 10 percent of the NAFTA base rate. This reduction began on January 1, 1994, with full duty elimination on January 1, 2003.

The Import Duty is calculated on the U.S. plant value (invoice) of the product(s) plus the inland U.S. freight charges to the border and any other costs listed separately on the invoice and paid by the importer such as export packing. In addition, a customs processing fee (CPF) of 0.8 percent is assessed on the total of the selling price of the product, inland freight cost, other fees (export packaging), plus duty paid and the custom broker fee, if this service is employed.

According to recent modifications in the Mexican customs law, the participation of a customs broker is not obligatory for imports if all legal and technical requirements are met. The participation of a customs broker is suggested when the exporter is not familiar with the Mexican standards and customs processing procedures.

A 15 percent value-added tax (IVA) is then assessed on the cumulative value consisting of the U.S. plant value (invoice) of the product(s), plus the inland U.S. freight charges, any other costs listed separately on the invoice such as export packing plus the duty. The importer will pay other IVA fees for such services as the inland Mexico freight and warehousing. The IVA is recovered at the point of sale.

***Distribution/Business Practices***

The distribution of refurbished medical equipment in Mexico is not developed. Most end users import equipment directly into Mexico, for their personal or institutional use.

Very few companies are legally registered with the Secretariat of Health to sell or distribute imported refurbished medical equipment. Companies involved in this business are mainly those offering repair service and equipment for lease. These firms advise end users on the equipment to buy. The end user negotiates the price and warranty with the foreign supplier. The equipment is imported by the end user and the Mexican company offers maintenance and repair service.

Sometimes, Mexican repair companies arrange with foreign suppliers to provide repair service to the end user as part of the equipment purchase contract.

Few repair companies have a product display area or stock equipment for immediate delivery. Only companies offering equipment for lease carry an inventory. It is common for leasing companies to offer a purchase option.

There are many American companies already selling refurbished medical equipment to Mexican hospitals. However, none of them have branch offices or exclusive representatives in Mexico. Many repair companies and distributors of new equipment sell only one or two medical equipment lines. Others include the selling of instruments or supplies.

***Service***

Service is one of the most important competitive factors for used and refurbished medical equipment. Most hospitals prefer to have permanent maintenance services and repairs accomplished within 24 hours. This means that spare parts and trained technicians must be available to respond adequately to client requirements.

It is important that new-to-market firms make a careful selection of a repair firm to represent the US firm and be sure that the Mexican company has the capability to provide timely and quality service.

Large distributors of new equipment usually have nationwide coverage; technical departments, a strong sales force and a solid financial background, but do not like to sell refurbished equipment.

# Moldova

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via E-Mail) 5 April 2001

According to the Ministry of Health and Customs Department, there are no restrictions for import [*but see conditions listed below*] and sale of used/refurbished medical equipment. Imports of used equipment are treated the same as new. Duties are charged based on the cost of the product. Documentary evidence of cost is preferred.

Generally speaking, three types of taxes are paid on all imports of medical equipment:

- Tax on customs procedures which typically constitutes 0.25 percent of the value of shipment;
- 20-percent value added tax;
- customs tariff tax which is 0% for most medical equipment.

Donated medical equipment is exempted from any customs duties.

The decision to allow certain medical equipment into the country is made on a case-by-case basis. The adequacy of any medical equipment brought into Moldova is assessed against an internal regulation of the Ministry of Health dealing with donated medical equipment. As a rule, the Ministry will allow into the country equipment less than ten years old (from the date of manufacture). The regulation sets the following requirements for medical equipment:

1. It should be accompanied by documents certifying the origin, quality, name and type of item, name of producer, date of manufacture, date of installation, name of the institution that has been using the equipment, date of de-installation, whether or not the equipment is operational, technical specifications and warranty period;
2. Any container should be accompanied by a document containing information on the number of packages, size, and weight;

3. Information has to be provided for each package concerning the name and type of the item, manufacturer, number of items in the package, date of packaging;
4. The cost of equipment has to be similar to the country of export or world level;
5. Proper operational guides must be provided.

The market for used/refurbished equipment in Moldova is extremely limited. However, Moldovan public health institutions use some small amounts of used equipment which has been donated by institutions and individuals from overseas, including the United States. Although prices for used/refurbished equipment tend to be significantly smaller that those for brand new equipment, the paying ability of Moldovan public health providers is still very small. Private health institutions are few and account for only a small portion of the health services market. Most purchases made by public health institutions are made through public tenders.

Few medical equipment distributors exist in Moldova. The state-owned company Moldtehoptimed is the most important provider of medical equipment. Separate licenses which are issued by the Ministry of Health are required for each of the following activities:

1. Dealing in medical equipment and
2. Importation of medical equipment.

# Morocco

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via E-Mail) 5 April 2002

### *Summary*

Approximately 20 percent of the total imported medical equipment is used or reconditioned. It consists of heavy equipment such as X-ray machines, magnetic resonance imaging apparatus, ultrasonic scanning apparatus, patient monitoring systems (except medical equipment that require direct contact with internal organs), surgery equipment and operating tables, sterilization equipment, bedding (except mattresses), etc. This equipment is used by private hospitals, known as 'clinics,' private specialty hospitals known as 'centers', such as radiology centers, cardiology centers, dialysis centers, private testing laboratories, etc. Reconditionned equipment with guarantees offers excellent opportunities.

### *Public Sector*

Under the Moroccan regulations, the public sector is required to purchase medical equipment through tenders. Although no law forbids purchase of used equipment, tender documents often require procurement of new equipment. Three government entities provide health care and purchase medical equipment. These are the Ministry of Health (Ministere de la Sante), the National Social Security (Caisse Nationale de Securite Sociale 'CNSS'), and the Ministry of Defense (Ministere de la Defense). They respectively provide health care through 'hospitals,' 'polyclinics' and 'military hospitals' and have independent budget and complete autonomy in purchasing medical equipment.

### *Regulatory Agency*

The Ministry of Health is the government agency in charge of the Moroccan healthcare system.

### *Regulations*

Under the Moroccan law 005/71 of October 12, 1971 on Protection against Ionization, import into Morocco of new or used radiology equipment requires a special authorization from the Center of Protection against Radiation of the Ministry of Public Health.

For used equipment, U.S. exporters must provide Moroccan buyers with the following:

- Compliance certificate
- FDA authorization
- Technical documentation/directions for use of the product
- Certification that the equipment is in good Electro-technical and radiological working order
- Documentation/history on previous maintenance.

### *Import Documentation*

Medical equipment and device other than radiation equipment requires approval from the Ministry of Health that the equipment meets Moroccan health standards. Morocco recognizes certifications provided by the FDA.

A commercial invoice is required. The commercial invoice should fully describe the goods in French. Certification as to country of origin is required. Payments are made through bank-to-bank irrevocable letters of credit. Pro-forma invoices must be provided in most cases. Invoices, which should be on company letterhead, are required for both import licenses and foreign exchange transfers. 'To order' bills are acceptable as bills of lading.

### *Labeling Requirements*

No special regulations apply to the exterior marking of containers for shipments to Morocco. Indication on outer containers of the net weight in kilograms, and other identification markings, will however assist in locating goods on arrival and speed their clearance through customs.

### *Import duties and taxes*

There are no restrictions or tariffs that apply to used or reconditioned medical equipment. New or used medical equipment is subject to 2.5-percent import duties paid on ad valorem. There is a value-added tax of 20 percent paid on the compounded ad valorem and import duties.

### *Standards*

Morocco uses the metric system exclusively and the 220 Voltage. Dates should have the date format dd/mm/yy. Literature in the French language is recommended.

### *Distribution*

Foreign firms sell into the Moroccan market through distributors/agents. Agents/distributors are often necessary to assist the U.S. firm with documentation in the French language. Key to success in the used medical equipment sector lay in the technical support and warranty given to end-users of reconditioned medical equipment.

## *Source:* IMI 5 August 1998

There are no restrictions on imports of used equipment in Morocco.

There are no special laws which impede importation of refurbished equipment. New or used equipment is imported freely into Morocco without any limitation in quantity and no discrimination of origin. All imports of used equipment are treated the same as new.

Only used clothes and used tires are prohibited from importation into Morocco.

***Market Assessment***

The Moroccan market for used equipment is small but expanding rapidly and we expect it to continue to grow over the next five years. The general receptivity of refurbished or used equipment within Morocco is moderate. The government prefers not to buy used equipment in order to avoid fraud, while private sector tends to buy it seeking substantial savings. U.S. equipment re-marketers have opportunities to export refurbished equipment in this market since U.S. technology is generally respected in Morocco for its quality and is perceived to be well in advance compared to major foreign competitors. Best prospects types of used equipment in Morocco are: medical, building and construction, construction, material handling, buses, vehicles, agricultural machinery, laboratory and scientific equipment and fishing boats.

***Comments***

In order to expand market share U.S. exporters of refurbished equipment should provide training to local technical personnel at the factory level to expand product knowledge. Key competitive factors bearing on each of the market positions are not only price but also equipment maintenance. U.S. suppliers should sell their used equipment in this market through well established local distributors with capable technical after sales service to install and maintain equipment and stock spare parts. User oriented documentation suited for local condition should be in French language if at all possible (product information in French is vital in Morocco). The end users' support staff are often ill-trained and prone to mishandle equipment if they don't receive initial instruction in French and are not provided with comprehensive manuals. U.S. exporters should be aware that the voltage used in Morocco is 110-220 v and 50 Hz.

There were very few cases where Moroccan customs did not accept the invoice price of refurbished equipment and imposed a higher evaluation. This possibility is not unique to importation of used equipment.

## Mozambique

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 5 April 2001 (Information confirmed 20 February 2002)

Regarding special restrictions or tariffs applied to used equipment, the Mozambican Customs Authority does not levy any restrictions. Used imported medical equipment is treated as new, and is liable for duties stated in the harmonized tariff in force.

Public health institutions can purchase used or refurbished medical equipment provided that it is in good condition. Maputo has sixteen private clinics and several hospitals that may be interested in used or refurbished d medical equipment at affordable prices.

### *Source:* Report from CS Post (via Cable) 31 March 2000 (Information confirmed 20 February 2002)

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

No, the Mozambican customs office does not apply any restrictions or tariffs to the importation of used medical equipment, although such products are liable to normal duties stated in the harmonized tariff schedule.

*Can public health institutions buy used or refurbished medical devices?*

Yes, they can purchase used or refurbished medical devices, provided they are in good condition.

*Is there a market for used or refurbished devices?*

Perhaps, although only at a low volume in a very limited number of institutions. Maputo has sixteen private the clinics that may be interested in used or refurbished medical equipment if offered at affordable prices.

## Nepal

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 12 April 2000 (Information confirmed 25 February 2002)

The Embassy polled the Procurement and Supply Division, Department of Health Services of the Government of Nepal and some private hospitals in Katmandu. Based on that information:

There are no restrictions or special tariffs on the purchase of used or refurbished medical devices/ equipment. Any government, private hospital or nursing home can buy used/refurbished medical devices. According to the Department of Health Services officia ls, government hospitals have accepted used equipment donated by foreign aid agencies in the past.

If imported, a normal customs tariff of 5 percent and value added tax of 10 percent is applicable. However, government procurements are exempted of such duties.

As Nepal is a poor country most of the government hospitals and even the private hospitals have minimal medical devices. Health care suppliers and manufacturers should consider it a small market with limited market potential for advanced health care items, but with a good potential for basic items.

X-ray machines, CT scan, and ultra sound machines can be regarded as best prospect products.

### *Source:* Report from CS Post (via Cable) 17 September 1998

Regarding the market for used and refurbished medical equipment, government hospitals, the major users of medical equipment, do not purchase used equipment. But, private nursing homes have gradually increased in number over the last 2 to 3 years in Nepal and these nursing homes may be interested in used and refurbished U.S. medical equipment. There are over two dozen private nursing homes now in Nepal. Dissemination of information about the availability of used medical equipment is lacking in Nepal.

## Netherlands

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via Cable) 27 August 1998 (Information confirmed 18 April 2001)

The Netherlands has no import restrictions specifically applicable to the importation of used equipment. Imports of used equipment are treated in the same way as new products.

The market for used and refurbished equipment plays a minor role in the Dutch economy. A relatively high standard of living combined with government incentives and tax deductions stimulate the purchase of new as opposed to used equipment. Equipment in the Netherlands is usually replaced long before its technical value has expired. In the respect, the Netherlands exports significant quantities of use equipment itself. Refurbished medical equipment is one area where there is potential for U.S. suppliers. Budget cuts and the necessity to save money on large capital outlays are forcing Dutch hospitals to consider purchasing refurbished equipment. However, there is still resistance to buying used medical equipment within the sector.

## New Zealand

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 2 May 2000

New Zealand's current legislation controlling the manufacture, import and distribution of medical devices (including used medical devices) is expected to change when the New Zealand and Australian Governments finalize their discussions on a joint therapeutic goods regulatory body. The discussions are still at a preliminary stage, but once the consulting process is completed and new legislation is passed by both the Australian and New Zealand Governments, no medical device will be accepted into New Zealand unless it is recorded on the joint register. There will be various criteria for a device to be accepted on the register. It is expected the proposed joint regulatory body will be operative in 1-2 years time.

Under the existing regulation, it is possible to import medical devices into New Zealand (provided they meet internationally-recognized standards) with very little Government intervention. The existing legislation does not require medical devices to be registered. The market relies on compliance by importers and manufacturers to established standards that is enforced by post-market surveillance. Medsafe is the Government agency that oversees the post-market surveillance.

Though existing legislation makes it possible to import used medical equipment into New Zealand Medsafe could intervene if it had concerns over the safety of used equipment. As a result and in view of this country's medical device legislation soon changing, medical device companies looking to do business in New Zealand should contact Medsafe first before entering this marketplace. The business contact details are:

Trevor Nisbet
Senior Adviser (Science)
Medsafe
Public Health Directorate
Ministry of Health
PO Box 5013
Wellington
New Zealand

Ph: 64 (4) 496-2364
Fax: 64 (4) 496-2599
Website: www.moh.govt.nz
Email: trevor_nisbet@moh.govt.nz

## Nicaragua

General Market Condition: No Restrictions, but Ministry of Health Does Not Buy

### *Source:* Report from CS Post (via Cable) 27 March 2000

According to the Nicaraguan Customs Department and Ministry of Health, there are no restrictions for the importation of new, used and/or refurbished medical equipment into Nicaragua. New, used and/or refurbished medical equipment have a zero percent tariff.

The Nicaraguan Ministry of Health only purchases new equipment. Local clinics and private hospital do purchase used or refurbished medical equipment.

Our assessment is that there is a market for used or refurbished equipment.

Best prospects include intensive care, surgical, laboratory and X-ray equipment.

Import of medical equipment from the U.S. into Nicaragua over the past three years is estimated at $8.3 million for 1997, $8.8 million for 1998 and $l0.0 million in 1999.

## Nigeria

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 2 May 2000

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

No.

*Can public health institutions buy used or refurbished medical devices?*

Yes.

*Is there a market for used or refurbished devices?*

Yes

*Best prospects?*

Scanners, diagnostic equipment, medical disposables and ECG equipment.

## *Source:* IMI Medical 9 March 2000

### Summary

Nigeria still depends on imports for most of its medical equipment needs. Local production is limited to peripheral items such as hospital beds and gurneys.

The Nigerian year 2000 budget is yet to be released, therefore this report is hinged on projections for 1999 which to the best of our knowledge is still very relevant. The Government of Nigeria will spend an estimated US$ 125 million on hospital equipment this fiscal year. It also restated its commitment to the resuscitation of the nation's health care delivery system through systematic funding and mobilization in line with the Bamako Initiative Program, a series of reforms in response to the deterioration of public health systems in developing countries. As in the previous years, private sector participation continues to account for much of Nigeria's imports in 1998, valued at approximately US$ 400 million.

The 1998 - 2000 national rolling plan objectives also include the completion of teaching hospital projects at Ahmadu Bello University, Zaria, University of Nigeria, Nsukka, and Ado Bayero University, Kano, rehabilitation of Ibadan University teaching hospital and equipment of several medical health centers and primary health care centers.

There is no doubt that the political situation and the resultant economic crunch had some negative effects on imports. However, with the change in government and possible political and economic reforms, this sector promises strong growth rates with an increasing demand for equipment such as analytical and examination instruments, ultra sound scans, anesthesia equipment, mortuary and laboratory equipment.

Nigeria's health policy is centered on primary health care delivered through an estimated 15,500 health institutions. The caption 'Health For All By The Year 2000', still remains the cornerstone of the Nigerian health care sector and therefore health care delivery is still high on the Nigerian government priority list. A number of projects are funded by the world bank under different loan agreements, especially for the rural areas.

The purchasing power of most Nigerian end-users is waning owing to devaluation of the national currency, and the widening gap between new technologies and developing economies. Refurbished and used equipment are therefore in high demand. A significant segment of this market in Nigeria is dominated by imports from Europe. However, U.S. Suppliers stand a good chance of competing successfully because Nigerians like U.S. equipment.

For further details, interested U.S. firms should contact the Commercial Service at the U.S. Embassy, Lagos, at the mailing address below:

The Commercial Service
U.S. Embassy, Lagos
Department Of State
Washington, DC 20521-8300

Tel. Number In Nigeria: 234–1-2610241
Fax Number In Nigeria: 234-1-2619856

## *Source:* Report from CS Post (via Cable) 2 October 1998

There are no regulations for importation of used equipment in Nigeria. Official guidelines relating to import duties, use of letter of credit for payment of imports and containerization of imports valued more than US$ 1,000 apply to both used and new equipment.

Import duties on used equipment are the same as for new. Duties are determined by the Nigerian customs service based on the invoiced value of equipment and an import duty report (IDR) issued by a government-appointed inspection agent.

Like several other imports, used equipment is often imported into Nigeria overland through third countries and ports, and as accompanied luggage of air travelers. Currently Nigeria's market for used equipment is dominated by imports from Germany, the Netherlands, Belgium, and the United Kingdom.

Price is the single most important driver of imports in this sector of the Nigerian market. Several local firms interested in used U.S.-origin equipment and parts including vehicles complain of high cost of importation from the United States, which according to them often results in an uncompetitive pricing strategy. Nigeria is a growth market for U.S.-origin products and services, but requires patience, resilience, a long-term relationship with a local partner (not a customer) and an export-cost strategy that recognizes Nigeria's large population but low per-capita income.

## Oman

General Market Condition: No Restrictions, but Ministry of Health Does Not Buy

### *Source:* Report from CS Post (via Cable) 29 March 2000 (Updated and Corrected by CS Post (via Cable) 2 April 2001)

The Ministry of Health is the main buyer of medical equipment in Oman. As a matter of practice, the Ministry of Health does not purchase used or refurbished medical equipment. Normally, when the ministry decides to purchase equipment, it contacts regular suppliers and requests the latest equipment; in some cases such purchases are conducted through tenders. Generally, equipment is purchased along with a minimum five-year maintenance contract.

Post does not know of any special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment.

Given the Ministry of Health's practice of purchasing new equipment only, prospects for sales of used and refurbished medical equipment in Oman remains extremely limited. It is possible that private hospitals and clinics could be potential purchasers of used medical equipment since their procurement does not go through the Ministry of Health. However, at this time, there are only two private hospitals in Oman.

## Pakistan

General Market Condition: Restricted

### *Source:* Report from CS Post (via E-Mail) 6 April 2001

Pakistan offers a promising market for used or reconditioned medical equipment and devices such as diagnostic equipment, electro-medical apparatus and laboratory equipment. Demand is expected to grow at an accelerated rate for items such as dialysis machines, diagnostic equipment, electro-cardiographs, scanners and X-ray apparatus.

In recent years, thousands of new medical centers have been set up all over the country. The majority of these private centers/clinics are run by reputable medical professionals. The increasing involvement of the private sector in health facilities is a positive development for U.S. suppliers of used medical equipment to consider marketing their products in Pakistan.

Under the import policy for 1999-2000, customs duty and sales tax on used medical equipment are as follows:

**Summary of Import Policy Order, 1999-2000 For Used Medical Equipment**

| HS Code | Description of Goods | Relevant Rules Under Import Policy Order 1999-2000 |
|---|---|---|
| 9018.1 to 9018.19 | Second hand or used surgical equipment like dialysis machines and electro-medical equipment | Import shall be allowed subject to the condition that these are not more than five years old. |
| 9018.13 | Second-hand/used diagnostic equipment | Import of this equipment shall be allowed if importer arranges for the foreign exchange resources. |
| 9018.19 | Testing equipment/analytical | |
| 9024 | Equipment including CT scanner | |
| 9026 | MRI equipment, etc. | |
| 9027 | Instruments for physical and chemical analysis | |
| 9030 | Instruments for measuring and testing electricity and electrical signals | |
| 9031 | Other measuring and checking instruments | |

### *Customs and Sales Tax*

Customs duty and sales tax on imported used medical equipment is as follows:

**Customs Duty and Sales Tax on Imported Used Medical Equipment**

| HS Code | Description Of Goods | Customs Duty (ad valorem) | Sales Tax on Imports |
|---|---|---|---|
| 9018.1100 | Electro-cardiographs | 10% | 15% |
| 9018.1200 | Ultrasonic scanning apparatus | 10% | 15% |
| 9018.3100 | Syringes with or without needles | 25% | 15% |
| 9018.9070 | Cine angiography film equipment | 10% | 15% |
| 9022 | Apparatus based on the use of X-rays | 15% | 15% |

### *Customs Duty and Tax Exemptions on the Items Imported by Non-Profit Institutions*

Below is a list of used medical equipment that, if imported by a charitable non-profit institution or by a hospital run by the Federal or provincial government, is exempt from customs duty and sales tax:

**Used Medical Equipment Exempt from Customs Duty and Sales Tax if Imported by Charitable, Non-Profit Institutions or Hospitals Run by the Federal or Provincial Government**

| HS Code | Description of Goods |
|---|---|
| 9018.11 | Electrocardiographs |
| 9018.12 | Ultrasonic scanning apparatus |
| 9018.13 | Magnetic resonance imaging apparatus |
| 9018.14 | Scintigraphic apparatus |
| 9018.19 | ETT machine, Echocardiography, Electro-cenephlograph, Radio-isotope scanners, |
| 9018.90 | Angioplasty balloon, Cardiac catheters, Endoscopy equipment |
| 9018.80 | Dialysis equipment |
| 9018 | Medical instruments |

## *Source:* ISA Medical 1 March 1998

Public sector hospitals procure medical equipment through tenders whereas private hospitals obtain these through distributors and suppliers who can ensure quality, technical services, and backup supplies. U.S. manufacturers benefit by appointing agents in Pakistan's major cities to market their superior quality products. Used/reconditioned equipment is often preferred as the private sector is price-driven. Import duties and sales tax were reduced in 1997.

Private sector health care is a significant factor in the market as more private hospitals are being established, generating a demand for imported equipment. Most private hospitals and clinics are set up as commercial ventures by local or expatriate Pakistani doctors. Most of these end-users seek either used or reconditioned equipment or, if new, they source it from the cheapest supplier.

The equipment listed above is imported either new or used. Generally, the following considerations are taken into account by end users when deciding between new or used machinery/equipment:

- Size—When the end user is a large hospital/organization, the preference is for new machinery/equipment.
- Value—When high value machinery is imported, and there is an appreciable difference in the price of new and used items, the preference is for used items, e.g. magnetic resonance imaging system, computerized tomography scanners.
- Basic Use Items—When the machinery/equipment to be imported is basic, involving simple technology, the preference is to import new items, e.g. ultra sound scanners, ophthalmic appliances.

## *Source:* ISA Laboratory 1 October 1998

Most laboratory and analytical equipment is being imported—either new, used or in reconditioned form. The general criteria for importing new machinery are low prices and appropriate technology. For example, basic items are imported new; the relatively expensive items are imported both in new and used forms. Larger hospitals generally prefer new items even if they are expensive, but the smaller laboratories or individual doctors prefer used items.

# Panama

General Market Condition: No Restrictions, but Public Institutions Can Not Buy

## *Source:* International Market Insight, *Commercial Opportunites for Used/Refurbished Medical Equipment in Panama*, 2 March 2002

### *Summary*

Panama offers good opportunities for exporters of used/refurbished medical equipment. Although government organizations by law cannot acquire used equipment, there is a potential market in the private sector, especially small to medium clinics and hospitals both in Panama City and in the interior of the country. U.S. medical equipment has an excellent reputation and is preferred by most doctors and hospitals. There are no restrictions/regulations for importing used medical equipment and import duties are relatively low. End Summary.

### *Body*

The Ministry of Health manages the health care system in Panama. Along with the Social Security System, it is responsible for procuring all of the medical equipment in the public sector. Private hospitals and clinics are the other main buyers of medical equipment in Panama.

There are no regulations, technical or safety standards applicable to new and used medical equipment in Panama. Both U.S. standards and European standards are accepted. Both used and new equipment is subject to the same treatment. By law, public institutions cannot buy used or refurbished equipment. The Panamanian international banking center offers excellent facilities for international trade transactions. The U.S. dollar is legal tender in Panama. No payment or exchange restrictions exist.

In 1998 import duties for medical equipment were lowered to an average of 10 percent, compared to the previous levels of up to 35 percent. Import duties in Panama are assessed over the CIF value. Additionally, a five percent value added tax is charged on the aggregate of the CIF value plus the import duty. Product reputation, as well as quality and service are the most important factors for end users when making a purchase decision, followed by price.

There are good market opportunities for used/refurbished medical equipment, especially in small hospitals and private hospitals both in Panama City and in the interior of the country. Products in greatest demand are imaging, x-ray, laboratory and diagnosis equipment.

For more information on Panama's health sector, please contact:

Ministerio de Salud
PO Box 2048
Panama 1, Panama
Tel: 507-225-6080
Fax: 507-227-5276
Contact: Fernando Gracia, Minister

## *Source:* Medical Device Regulatory Requirements for Panama, 21 February 2001

*Report prepared by the U.S. Commercial Service Post, Panama*

### *Regulatory Agency*

The Ministry of Health manages the health care system in Panama. Along with the Social Security System, it is responsible for procuring all of the medical equipment in the public sector. The private hospitals and clinics are the other main buyers of medical equipment in Panama.

### *Regulations*

There are no regulations, technical or safety standards applicable. Both U.S. standards and European standards are accepted in Panama.

### *Import Duties and Taxes*

In 1998 import duties for medical equipment were lowered to 10 percent, compared to the previous levels of 35 percent and 27.5 percent. Import duties in Panama are assessed over the CIF value. Additionally, a 5 percent value added tax is charged on the aggregate of the CIF value plus the import duty.

### *Used Equipment*

There are no special restrictions or tariffs for used medical equipment. Both used and new equipment will be subject to the same treatment. By law, public institutions cannot buy used or refurbished equipment.

There are some market opportunities for used/refurbished medical equipment, especially in small hospitals and private hospitals in the interior of the country. Products in the greatest demand are: imaging, X-Ray and diagnosis equipment.

### *Contact Information*

| Government Agencies | Trade Associations |
|---|---|
| Colon Free Zone Administration<br>PO Box 1118<br>ZLC, Panama<br>Phone: 507-445-1033<br>Fax: 507-445-2165<br>E-mail: zonalibre@zolicol.org<br>Contact: Jorge Fernandez, Director | American Chamber of Commerce & Industry of Panama (AMCHAM)<br>PO Box 74<br>Balboa, Panama<br>Phone: 507-269-3881<br>Fax: 507-223-3508<br>E-mail: amcham@sinfo.net<br>Contact: Richard Wainio, Executive Director |
| Caja de Seguro Social<br>PO Box 1393<br>Panama 1, Panama<br>Phone: 507-261-8002<br>Fax: 507-261-2208<br>Contact: Juan Jovane, Director | Asociacion de Usuarios de la Zona Libre de Colon<br>PO Box 3118<br>ZLC, Panama<br>Phone: 507-441-4878<br>Fax: 507-441-4347<br>E-mail: au@sinfo.net<br>Contact: Galo Pinto, Executive Director |
| Ministerio de Comercio e Industrias<br>Viceministerio de Comercio Exterior<br>PO Box 61897<br>El Dorado, Panama<br>Phone: 507-236-0511<br>Fax: 507-236-0521<br>E-mail: vicomex@mici.gov.pa<br>Contact: Meliton Arrocha, Vice-Minister | Panamanian Chamber of Commerce, Industry and Agriculture<br>PO Box 74<br>Panama 1, Panama<br>Phone: 507-225-4615<br>Fax: 507-225-3653<br>E-mail: cciap@panama.phoenix.net<br>Contact: Jose Ramon Varela, Executive Director |

| | |
|---|---|
| Ministerio de Economia y Finanzas<br>Direccion General de Aduanas<br>PO Box 1671<br>Balboa, Ancon<br>Phone: 507-232-5355<br>Fax: 507-232-6494<br>Contact: Mercedes Villalaz, Director | Sindicato de Industriales de Panama<br>PO Box 64798<br>El Dorado, Panama<br>Phone: 507-230-0284<br>Fax: 507-236-0166<br>E-mail: sip@sinfo.net<br>Contact: Daniel Vega, Executive Director |
| Ministerio de Salud<br>PO Box 2048<br>Panama 1, Panama<br>Tel: 507-225-6080<br>Fax: 507-227-5276<br>Contact: Jose Teran, Minister | |

## *Source:* Report from CS Post (via Cable) 6 March 2000

### *Overview*

Post reviewed the 1999 edition of this report and found the Panama entry (*see below*) to be accurate.

### *Response to Specific Questions*

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

No special restrictions apply to used medical equipment in comparison to new equipment.

*Can public health institutions buy used or refurbished medical devices?*

Public health institutions can not buy used or refurbished equipment. By law, the government can buy only new equipment.

*Is there a market for used or refurbished devices?*

There is a market for used and refurbished equipment.

*Best prospects?*

Best prospects are: diagnosis equipment, imaging equipment, X-ray equipment.

## *Source:* ISA Medical 1 April 1999

### *Summary*

Panama's medical equipment market is estimated at $33.6 million in 1999, an increase of 5 percent from 1998. This sub-sector experienced significant change during the mid 1990s. Since 1996 the number of hospital beds has increased by 1,000 in the country, to about 8,200 beds in 1999. Both public and private hospitals have been built and old ones have been upgraded. The public sector is the primary end user of medical equipment. It is divided into two segments: the Ministry of Health System and the Social Security System. The private sector is strong and has state-of-the-art medical facilities.

There are no regulations, technical or safety standards applicable. Both U.S. standards and European standards are accepted in Panama. Good transportation and communications facilities are available in the country. The international banking center offers excellent facilities for international trade transactions. The U.S. dollar is legal tender in Panama. No payment or exchange restrictions exist.

Most medical equipment is subject to a 10 percent import duty, plus a 5 percent value added tax, assessed on the CIF price plus the import duty.

### *Competitive Factors*

According to industry sources, product reputation, as well as quality and service are the most important factors for end users when making a purchase decision, followed by price.

There are some market opportunities for used/refurbished medical equipment, especially in small hospitals and private hospitals in the interior of the country. The government does not purchase used or refurbished equipment.

### *End-User Analysis*

There are two groups of medical equipment users. The first group is the public sector. This group is in turn, divided into two segments: the Ministry of Health System and the Social Security System. The second group is formed by private hospitals and clinics. Other users are small private clinics with less than 20 beds.

Of the two segments in the public sector, the Social Security System enjoys a more generous budget, because Social Security affiliation is mandatory for all Panamanian workers. Government procurement practices, however, apply in both segments making the purchase of medical equipment a very lengthy process. Recently, the government has implemented a new administrative model for one of the newly constructed hospitals, the San Miguel Arcangel Hospital. Its administration has been put in the hands of a private company. This system will assure that patients cover part of the cost of their medical care, according to their own economic situation. The procurement procedures will also be more efficient than the one currently in use for public hospitals. It is anticipated that the model will be implemented in the rest of public health system. This will bring more competition and efficiency to the medical equipment market.

### *Import Climate*

There are no regulations, technical or safety standards applicable to medical equipment in Panama. U.S. standards, and other international standards are accepted.

## Paraguay

General Market Condition: No Restrictions, but Public Institutions Can Not Buy

### *Source:* Report from CS Post (via Cable) 31 March 2000 (Information confirmed as still valid, 23 March 2001)

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

Paraguay has no special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment.

*Can public health institutions buy used or refurbished medical devices?*

Public health government institutions can not buy used or refurbished medical devices.

*Is there a market for used or refurbished devices?*

Yes, there is a market for used or refurbished devices in the private sector.

*Best prospects?*

Best prospects are all types of diagnostic imaging equipment.

## Peru

General Market Condition: Restricted in Practice not Law

### *Source:* Report from CS Post (via Cable) 5 April 2002

***Summary***

There is no explicit restriction on the importation of used/refurbished medical equipment into Peru. However, as a matter of practice over recent years, the Directorate General of Pharmaceuticals, Inputs and Drugs (*Dirección General de Medicamentos, Insumos y Drogas*—DIGEMID) of the Ministry of Health is not authorizing the import of used medical equipment and devices.

By law, public health hospitals, social security hospitals and armed forces hospitals can buy only new medical equipment and devices. Private sector clinics and hospitals can purchase used medical equipment.

Imports of general used equipment are treated the same as imports of new equipment. Under General Health Law No. 26842, imports of medical equipment and devices require a 'Sanitary Registration' issued by DIGEMID of the Ministry of Health. It is necessary to obtain the Certificate to Foreign Governmen' from the U.S. Food and Drug Administration (FDA) to be able to get the Sanitary Registration. The inspection certificate issued by one of the three authorized companies, i.e., SGS, COTECNA, and Bureau Veritas, is also required. These companies charge US $250 for imports valued from $2,000 to $25,000 and 1 percent for imports valued overr US $25,000.

Both new and used products pay 7-percent or 12-percent custom duties applicable on the CIF value, in addition to the 18-percent sales tax.

In addition, the Customs Circular 1071 dated September 16, 1999, states that the Sanitary Registration is mandatory to release the products from customs. However, as a matter of practice DIGEMID only issues the Sanitary Registration for new medical equipment. The latter circular only authorizes the import of used medical equipment when it is for the immediate use by a professional returning to Peru.

## Philippines

General Market Condition: Restricted, but Public Institutions Can Not Buy

### *Source:* Report from CS Post (via E-Mail) 1 July 2002

Medical Device Regulatory Requirements for the Philippines, July 1, 2002

There are no special restrictions on the importation of medical equipment provided these are imported by duly authorized and licensed medical equipment importers and distributors. Importers/Distributors must secure this License to Operate (LTO) from the Department of Health.

The Bureau of Health Devices does not impose any restriction on used medical equipment except that these should be comparable in safety with new equipment. Refurbishers of used equipment

must obtain a clearance from the original equipment manufacturer and must conform to good manufacturing practices. Refurbishers are also not allowed to distribute commercially, any device that has not been produced in conformity with such requirement.

Only X-ray machines and other radiation-emitting devices require registration before introduction to the local market. Local testing is required only for certain radiation equipment like the Linear Accelerator.

The validity period for initial registration of a medical device is one year. Under Bureau of Food & Drug Administration (BFAD) Circular #05, series of 1998, length of renewal registrations has been extended to five years.

The Bureau of Health Devices and Technology under the Department of Health is the primary agency that monitors medical equipment (ionizing and non-ionizing, radiation dosimetry, radiation, non-radiation, laboratory, medical physics, etc.)

The Philippines imposes a 3-percent tariff duty and a 10-percent value-added tax (VAT) on imported medical equipment, including used and refurbished. As a policy, however, the government can only procure new equipment.

The Department of Health or the health units under the local government supervision may, however, accept used equipment if these are donated, provided the equipment includes an operation manual to ensure its safe operation. The government discourages Philippine importers from buying used equipment without proper documentation and operation handbook.

There are good opportunities for used/refurbished medical equipment: it accounts for 40 percent of the Philippine market. Like new equipment, the most promising sub-sectors are X-ray equipment and medical/surgical instruments. Major end-users are the primary and secondary hospitals in Metro Manila and the provinces.

There are 3 classifications of Philippine hospitals:

- Primary Hospitals—capable of handling general medicine, pediatrics, obstetrics and minor surgeries;
- Secondary Hospitals—can handle all services available in a primary hospital including gynecology, general surgery, and other ancillary services;
- Tertiary Hospitals—fully departmentalized hospitals that can handle more specialized services than secondary hospitals.

### *Contact Information*

Department of Health of the Philippines:
San Lazaro Compound, Tayuman, Sta. Cruz
Manila, Philippines 1003

Website: www.doh.gov.ph/bfad

Organization E-mail: bfad@mc.pworld.net.ph

Telephone: (63-2) 743-8301; 711-6016
Fax: (63-2) 711-6824

### *Contacts*

Dr. Manuel Dayrit
Secretary, Department of Health

Ms. Agnette P. Peralta
Director, Bureau of Health Devices and Technology

Engineer Cecilia Matienzo
Engineer V, Bureau of Health Devices and Technology

# Poland

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via E-Mail) 28 March 2002

### *Import Regulations for Used Medical Equipmen in Poland*
### *Prepared by Zofia Sobiepanek*

There are no restrictions in Poland on imports and/or the purchase of used medical equipment by either state-owned or private health care facilities, but market opportunities for second-hand equipment are very limited. Used equipment purchases are made but no specific buying pattern has been identified. Leasing of medical equipment is not wide spread in Poland. Moreover, the market for used/refurbished medical equipment is also very limited. However, with an increasing number of private clinics and financial limitations within the public health care sector their sales prospects might improve significantly in the next few years.

Currently, the Polish government's policies are aimed at meeting requirements for European Union (EU) membership. Polish authorities are being pressured from many sources to adopt European Union standards and to accept, without further testing, all products that are certified in EU countries. However, at this time it is difficult to foresee when such a policy change will be in effect. Therefore, one of the best strategies for American companies interested in selling medical devices in Poland is to find a local partner who can assist them in responding properly to tender offers and with the existing procedures required to sell equipment in Poland.

Because it is difficult to make a one-time sale of medical equipment, Polish partners prefer to work with foreign suppliers on a long-term basis. Price is also a key factor considered by potential buyers. Important too is the local availability of services and spare parts. Quality is usually the next element considered, and U.S. products are usually viewed favorably.

In Poland, doctors recommend medical products. A good marketing strategy is to keep them well informed about products. This means that a successful company will need to have a distributor who can raise awareness of new products, attend medical seminars and conferences, and keep doctors informed by direct contacts or mail campaigns.

### *Registration/Certification*

Currently, medical equipment, new and used, for use in public hospitals and/or private clinics and medical centers must be certified by the appropriate Polish authorities. Any equipment offered in public tenders must have initiated the registration procedure in order to be permitted to participate in a tender, and the procedure must be completed before any contract is signed. It is crucial to have a Polish partner or representative to assist with what is generally a complicated certification process.

The certification requirement is regulated by the Minister of Health and Social Welfare's Regulation on Certificates of Medical Apparatuses and Equipment acquired by Health Care Institutions of March 11, 1992, which can be found in government publication Dziennik Ustaw (Journal of Law), Dz. U. 31/92 item 135.

A company registered in Poland must make the request for registration. The applicant may be an authorized representative or a distributor of a foreign supplier. All equipment is tested technically. If the producer is not already known by the certification agency, or the equipment is complicated, it may also require clinical tests. Certification is issued for a period of five years with the possibility of extending it for another three years. Medical equipment does not require additional tests for the Polish 'B' safety certificate, which is required for many other types of equipment.

American exporters should be aware that electrical voltage in Poland is 220 and the current frequency is 50 Hz. Power cables and plugs must be consistent with Polish standards. Labeling and instructions for use (operation manual) must be in Polish language. Technical documentation and certificates as required for submission can be in one of the following languages: English, German or French.

The following office is responsible for certification of medical equipment:

Centralny Osrodek Techniki Medycznej
(Central Medical Technology Center)
ul. Boduena 4
00-950 Warszawa, Poland
Tel: +48/22 827-80-51 ext. 41
Fax: +48/22 827-87-91
Contact: Dr. Marian Nowicki, Chief, Certification Department (Kierownik Biura Atestacji)

Once the new law on medical products is implemented (which is expected to happen sometimes in 2002), the above regulations will no longer be in force. The Healthcare Products Registration Agency will replace the Central Medical Technology Center. Under the new law, most of the regulations will be harmonized with the European Union's Medical Device Directives. However, the CE mark will be accepted for Class I (low-risk) products that do not need testing by a certified body in any country. Since Poland will still operate as an independent market separate from the EU, some local regulatory requirements will remain in place until Poland becomes a full EU member. Manufacturers from third countries, including the United States, will need to have their products tested and certified by the Healthcare Products Registration Agency until Poland joins the EU.

### *Tariffs*

There are no differences in tariffs for new or used medical equipment.

Poland complies with the Harmonized Tariff System. Tariff rates are subject to change annually (in January). Depending on the country of origin, products are divided into three categories: developing nations, members of the World Trade Organization, and countries with which Poland has a bilateral or multilateral customs agreement (e.g., free trade agreements, CEFTA). In 1992, Poland signed an Association Agreement with the European Union (EU) that lowered or eliminated tariffs on many EU produced goods imported into Poland. Tariffs on U.S. products did not change. At that time, the U.S. managed to negotiate more favorable rates for some product categories, but many U.S. products are still at a tariff disadvantage compared to EU competitors. Customs rates (duties) are based on the CIF value of the product. Customs officials are extremely strict with regards to proper documentation. It is essential that exporters take care to fill out documents properly to avoid costly delays in customs clearance.

### *Tariff rates*

Customs duties apply to all products imported into Poland. The Polish tariff schedule has different rates for the same commodities depending on their country of origin. Revisions to the

Polish tariff rate schedule are made annually. American companies generally face unfavorable customs tariffs compared to imports from European countries. While the customs tariff for medical equipment and supplies imported from the U.S. varies from 3 percent to 9 percent, EU and EFTA equipment is completely exempted from customs duty.

In addition to the above tariffs, a value-added tax (VAT) of 22 percent is added regardless of origin.

### *Best Sales Prospects*

The current Polish health care system operates on the basis of dual financing. The owners of public hospitals and clinics, the local governments, finance major investments such as equipment purchases, construction and maintenance of the facilities. The Sick Funds are responsible for financing the operating costs of the health care system in Poland, i.e. the daily costs of the primary care, outpatient and in-patient care, as well as reimbursement for medicines and rehabilitation products. The Sick Funds operate on the actual, current contributions of employers and employees. The Ministry of Health directly finances clinical academies and research hospitals and specialist institutes, and prepares and is responsible for healthcare education.

Poland's budgetary constraints heavily influence the public health sector. In year 2000, Poland spent 4.24 percent of GDP on health care. Healthcare costs accounted for 4.3 million PLN (about 1 million USD), which represents 2.85 percent of the state budget. Local governments spent 2.7 million PLN (about 675 thousand USD), which represents 3.6 percent of their annual budgets. The main healthcare payers, Sick Funds, spent 23.8 million PLN (about 6 million USD) in 2000.

Private clinics can purchase medical equipment independently from any source they wish or through any trading organization they choose. Privatization of healthcare services in Poland has proceeded most rapidly in ambulatory and diagnostic imaging services and outpatient care. There are a great number of small private outpatient clinics providing one-day-surgery, cosmetic surgery, medical check-ups, lab tests, etc., where patients pay either out of their own pocket or through private health care packages offered by major companies as a fringe benefit to their employees.

The U.S. Commercial Service (CS) Warsaw has identified the following best prospects in medical equipment sector for the Polish market:

- Ultrasonography equipment
- Endoscopy equipment
- Hospital sterilization equipment
- Monitoring equipment for use in intensive care
- Emergency medicine
- Oxygen therapy

In addition to the above-listed categories, rehabilitation equipment is also a good prospect for U.S. suppliers. Access to most private and public buildings and to public transportation is still a serious problem. There is a critical need to reduce physical barriers in order to enable disabled people to live better lives and to function more easily in society. Also, there is a demand for high quality home-care products and accessories.

Investment type purchases, such as advanced medical equipment like mammography equipment, EEG equipment, Magnetic Resonance Imaging units, radiography/tomography Units, X-ray equipment, etc., are currently extremely limited.

### *Additional Information*

For further information regarding medical sector in Poland, please contact the U.S. Commercial Service, American Embassy Warsaw, Poland. We offer a wide range of programs to open the Polish market to Amercian companies. For more information about what we do and how we do it, please take a look at our website: www.buyusa.org/Poland (it will come up in Polish, but you can click on the English version).

**Mailing address (from the U.S.):**
5010 Warsaw Place
U.S. Department of State/FCS
Washington, DC 20521-5010

**Street address:**
U.S. Commercial Service
Al. Jerozolimskie 56 C
00-803 Warsaw, Poland
Tel:+48/22 625-4374
Fax: +48/22 621-6327
Contact person: Zofia Sobiepanek, Commercial Specialist
e-mail: Zofia.Sobiepanek@mail.doc.gov

### *Source:* Industry Sector Analysis, *Medical Device Payment/Reimbursement*, 29 March 2002

Leasing of medical equipment is not wide spread in Poland. Moreover, the market for used/refurbished medical equipment is also very limited. However, with an increasing number of private clinics and financial limitations within the public healthcare sector, their sales prospects might improve significantly in the next few years.

Currently, medical equipment, new and used, for use in public hospitals and/or private clinics and medical centers must be certified by the appropriate Polish authorities. Any equipment offered in public tenders must have initiated the registration procedure in order to be permitted to participate in a tender, and the procedure must be completed before any contract is signed. It is crucial to have a Polish partner or representative to assist with what is generally a complicated certification process.

## Portugal

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via E-Mail) 27 March 2002

Portugal is governed by the EU harmonized legislation/directive which covers the importation of new and used medical devices to Europe. The importation of new and used medical equipment for use in public hospitals and/or private clinics and medical centers must be certified by the appropriate Portuguese authorities. These devices, when imported from third countries to be sold in Portugal, have to undergo a complicated certification process by a credited entity in the EU. If devices pass this certification, they are marked 'CE' and may move freely and be sold in all countries in the EU.

This EU directive primarily focuses on certain minimum requirements for the medical devices entering Portugal. All credited organizations are attributed a 4 digit identifying code by the European Commission. In Portugal, the official entity that is credited to attribute the CE mark is:

LEMES-Laboratorio de Ensaios Metrologicos de Equipamento de Saude
Av. Padre Cruz
1699 Lisboa Codex
Tel: (351-21) 757-5853 / 757-3557
Fax: (351-21) 757-3671
Contact: Eng. Faria Gomes, President

## Romania

General Market Condition: No Restrictions, but Public Institutions Can Not Buy with State-Guaranteed Loans

### *Source:* Report from CS Post (via E-Mail) 28 February 2002

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

Customs tariffs for used equipment are similar to the ones for new equipment

The Ministry of Health and Family (Ministerului Sanatatii si Familiei—MSF) does not acquire refurbished medical devices through sovereign guarantees

The refurbishment program applies to the existing pieces of equipment already operational on the Romanian market

*Can public health institutions buy used or refurbished Medical devices?*

MSF is not allowed to make purchases in a centralized manner based on state guaranteed loans.

*Is there a market for used of refurbished devices?*

In Romania there is a market for used or refubished medical devices, but this is currently not well-defined.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

As the size of this market has not been determined yet, it is difficult to establish its structure. Checking up on the private market of medical services may be beneficial although it is unlikely that a relevant database might exist.

## Russia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 26 March 2002

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

There are no special restrictions or tariffs that apply to used equipment. The most common tariff for medical equipment is 5 percent. There are only a few exceptions to that tariff rate. They concern imported disposable syringes, except for ones used to inject insulin (15 percent), IV solution transfusion systems (15 percent) and hydro massage bath tubs. The tariffs apply to the product category and are the same for new and used medical equipment and devices, which belong to the same category.

*Can public health institutions buy used or refurbished medical devices?*

Public Health Institutions can buy used medical equipment, but it is not in large demand as far as we can judge. Please note that Russian distributors and healthcare institutes can only buy used medical equipment which was registered by the Ministry of Health and certified by Gosstandart when the equipment was new. The Ministry of Health will only consider new medical equipment for registration. Subsequently, only medical equipment that has been registered can be resold as used.

*Is there a market for used or refurbished devices? Best prospects?*

The market for refurbished medical equipment is very limited. Russian health care priorities have focused more on high technology 'cutting edge' medical products than on preventive medicine and basic medical needs. Regional health authorities responsible for procurement of medical equipment in their respective regions prefer to buy brand new medical equipment as they receive a percentage of the purchase price as a reverse commission on the transaction. According to our estimate, used medical equipment accounts for only 5 percent of the total medical equipment market. Refurbished medical equipment is usually handled by private medical equipment distributors, which work directly with clinics and hospitals.

*What type of used or refurbished medical equipment are in the greatest demand?*

The best prospects for used equipment include X-ray equipment, magnetic resonance imaging, ultrasonic and laboratory diagnostic equipment.

## *Source:* IMI Medical 23 May 2001

### *Summary*

Russia would appear to have the potential to sustain a healthy market for used medical equipment, particularly for equipment used in the manufacture of pharmaceuticals. Domestic Russian pharmaceuticals manufacturers are currently enjoying very favorable market conditions. To date, however, sales of imported used medical equipment have proved disappointingly small. The difficulty of meeting the mandatory registration and certification requirements, in a system not geared to deal with foreign-source used equipment, acts as a constraint. So too does the fragmented structure of the used market and the lack of servicing support from foreign suppliers. These difficulties need not be insurmountable, and Russia has an abundance of inexpensive, skilled and easily trained technicians able to support medical equipment refurbishing and assembling operations.

### *Body*

The Russian market possesses many of the characteristics which should make it attractive to suppliers of used medical equipment. It has a large population (145 million), many of whom are aged. The state healthcare system suffers significant budgetary constraints, and is limited in its ability to purchase expensive new equipment. Local equipment manufacturers have made few technological advances over the last decade and consequently cannot offer the most advanced equipment.

The total size of the Russian medical equipment and supplies market is currently estimated at about US $2 billion, and has been growing rapidly. Since the August 1998 economic crisis, this growth has exceeded even the robust rates of growth of the Russian pharmaceuticals market. However, the market for used medical equipment has proved disappointing to date. According to the author's estimate, based on consultations with industry experts and distributors, used equipment accounts for only 5 percent of the total market for medical equipment.

The market for refurbished medical equipment is very limited. While public health institutions and the many regional health authorities are permitted to buy imported used medical equipment, they usually prefer to focus on new and often expensive 'cutting edge' technology. It has even been reported that, in some cases, the desire by procurement staff to receive informal incentive payments from suppliers may have driven the decision to purchase such equipment. Equipment for use in the provision of basic and preventative medicine is typically procured from local manufacturers.

The mandatory registration and certification requirements for imported equipment are not geared to used equipment and can be difficult, if not impossible, to satisfy. Russian distributors and healthcare institutes are permitted to purchase only used medical equipment which has been registered by the Ministry of Health and certified by Gosstandart, the Russian state standards agency. The Ministry of Health will register only new medical equipment, not refurbished equipment. This means that, if a certain make and model of new medical equipment has been registered previously, then refurbished models may be sold. Otherwise the used equipment cannot be sold in the Russian market. As for certificates of conformity, such certificates can be obtained from certification centers accredited by Gosstandart. With regard to customs regulations, there are no special restrictions or tariffs that apply to used equipment, once it is certified. The tariffs apply to the product category and do not differentiate between new and used medical equipment and devices, with the most common tariff for medical equipment being 5 percent.

The steep devaluation in the ruble in the aftermath of the August 1998 economic crisis made imports more expensive and resulted in the increased competitiveness of Russian manufacturing industry. Russian pharmaceutical equipment manufacturers have managed to compete against imports in a period when their customers, the Russian pharmaceutical companies, were similarly enjoying enhanced competitiveness. In 2000 alone, local pharmaceutical production increased by 20 percent and today local manufacturers supply over 45 percent of the total market, taking advantage of the sharp rise in prices of imported Western drugs. Many Russian pharmaceutical factories are in need of new and replacement equipment, including packaging and labeling equipment, and it is in this area that some reasonable sales prospects exist for foreign suppliers of used pharmaceutical manufacturing equipment. The Commercial Service works with the Russian Association of Pharmaceutical and Medical Equipment located in St. Petersburg to collects leads from Russian pharmaceutical manufacturers for foreign reconditioned production equipment.

In the case of used medical equipment for disease treatment, maintaining and servicing such equipment in Russia is problematic. Even though local labor costs are low, and the supply of proficient and trainable technicians abundant, the cost of new replacement parts and components can be prohibitively high. As a rule, local companies specializing in refurbishing used medical equipment have to buy new spare parts from the original manufacturer, as such parts are not produced locally. In some cases, the price of a replacement part can be higher than the purchase price of the used equipment itself. The problem is often compounded by the absence of long-term, direct relations between foreign suppliers and local medical equipment refurbishers. Shipments in the past have tended to be infrequent and were typically handled through intermediaries lacking the capability to provide adequate servicing and maintenance support. In some cases, Russian buyers of used medical equipment sustained losses as many spare parts were not available, and consequently the equipment was impossible to refurbish. The above problems

not withstanding, the best prospects for used equipment in this area include X-ray equipment, magnetic resonance imaging, ultrasonic and laboratory diagnostic equipment.

Because labor costs in Russia are much lower than in the West, several companies have found it cost effective to assemble equipment locally from imported components, rather than import finished product. A significant portion of production equipment for the pharmaceutical industry is assembled locally. The leading Russian company which specializes in refurbishing and maintaining used Western medical equipment is Izomed. This firm is seeking to establishing long-term cooperation with Western manufacturers based on at least a 6-month warranty period and servicing contracts. Another organization which is interested in cooperation with Western suppliers of refurbished medical equipment is the newly created Soyuzmedprom Association, which unites major Russian manufacturers and distributors of medical equipment.

It is not inconceivable that a well organized and well financed used medical equipment supplier could overcome the obstacles currently a feature of the Russian market to emerge successful, or that niche players might find profitable roles for themselves. At present, however, the current market structure and regulatory environment are not favorable for the others.

This information is provided to you by the Commercial Service (CS) in Moscow, part of the U.S. Embassy, which offers to U.S. exporters a number of services aimed at generating export sales, including identifying distributors and arranging meetings with prospective buyers during business visits to Russia. The CS Moscow, encourages U.S. companies wishing to do business in Russia to utilize its Gold Key Service. Experienced Commercial Specialists identify opportunities, arrange business appointments with pre-qualified Russian agents and distributors, and accompany you to the meetings. Gold Keys cost $600 (basic prices) or $1,200 (full logistical support price) for a full day of appointments (typically 4), and $300 (basic price) and $630 per additional day. Logistical support includes assistance with reservations at suitable hotels, several of which provide discounted rates to CS clients; airport pick-up/drop-off; ground transportation to meetings; and interpreter services for 8 hours a day. The Commercial Service requires sufficient company literature and price lists at least three weeks prior to the desired appointment dates, and accepts payment by VISA, MasterCard, American Express and Discovery cards. Additionally, as part of CS' regional cooperation program, CS Moscow will share your Gold Key inquiry with other offices, who may contact you directly. For more information on FCS Moscow services, U.S. companies may visit our website at: www.usatrade.gov or the BISNIS site at: www.bisnis.doc.gov or contact us directly.

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### *Source:* International Market Insight, *Healthcare Services, Medical Equipment and Supplies, and Pharmaceuticals Market in the Russian Far East,* 22 March 2001

Dental equipment and supplies are in growing demand on the local market. The poor fluorite level in local water and tough climate conditions presuppose a larger than average need for dental services in Russia. All dental equipment and supplies are imported. At the same time, dental clinics are usually private, market-oriented and profitable. The combination of these factors makes this subsector rather attractive for U.S. exporters.

Despite an obvious under-financing of this subsector [dental], used and second-hand medical equipment have very limited sales potential on the Russian Far East (RFE) market due to certification and other administrative impediments.

There is some potential though for pharmaceuticals' manufacturing equipment.

### *Source:* ISA Medical 1 January 2000

#### *Home Healthcare Products and Equipment: Best Sales Prospects*

In general, the Russian population and health care and social protection authorities prefer to buy new home healthcare products and equipment, therefore, used products and equipment are not in high demand.

### *Source:* ISA Medical and Dental 1 March 1999

#### *Best Sales Prospects*

Because many types of dental equipment and supplies, which are needed for treatment, are not produced locally, there will be unsatisfied demand for many types of products for the next three years. According to data provided by the Russian Dental Association, the best sales prospects in the Russian dental equipment and supplies market include:

- dental units
- dental X-ray equipment
- pastes for filling root canals
- equipment for dental orthopedics
- dental porcelains
- dental films and chemicals
- adhesive systems
- photopolimerizers
- dental disposable supplies
- dental anaesthetic gels & solutions
- anchorage pin systems
- composite filling materials

In general, Russian dental clinics prefer to buy only new dental equipment therefore used dental equipment is not in high demand.

## Saudi Arabia

General Market Condition: No Restrictions, but Ministry of Health and Government Hospitals Do Not Purchase

### *Source:* Report from CS Post (via Cable) 9 September 1998

There are no Saudi standards nor any specifications that apply to used or refurbished medical equipment. The Ministry of Health and other Saudi government hospitals will, however, abstain from purchasing such equipment. Other clinics and hospitals might purchase the same only from an established local agent who should be able to provide maintenance and spare parts for 10 years. The only standard that applies relates to electrical specifications, i.e. 110 V, 60 Hz.

## Serbia and Montenegro

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 23 July 1998

The Former Republic of Yugoslavia (FRY) permits the importation of used equipment other than vehicles and construction equipment. Tariffs are generally the same or slightly higher than for new equipment of the same type. Vehicles equipped with medical equipment may be imported if they are not more than 4 years old.

The used equipment market in the FRY is relatively new and undeveloped. Most large firms are socially owned and appear to be adverse to purchases of used equipment. Reports indicate that price is often not the primary criterion for decision makers of such firms. Smaller firms appear to have some interest in used equipment, but face bureaucratic hurdles and possess low purchasing power. The Serbian government recently decided to prohibit imports of used clothing, which was beginning to gain a foothold in the FRY. This ban sends a cautionary signal about prospects for significant development of the used equipment market, although the ban may be an isolated case since it was part of a set of actions taken to reduce imports of consumer goods.

## Senegal

General Market Condition: No Restrictions, but Public Institutions Do Not Buy

### *Source:* Report from CS Post (via Cable) 6 April 2001

The market for used/refurbished medical equipment in Senegal is very limited, if not non-existent. In a country where the public sector is the biggest purchaser and user of medical equipment, major impediments to the sale of used medical equipment remain, due to public procurement procedures and to technical constraints.

In the public sector, all purchases of medical equipment are made either through international tenders financed by the World Bank and other multilateral donors or they are financed by the Senegalese government's special investment budget. A stringent requirement is that the equipment be new.

The technical constraints essentially concern the norms and standards. The Senegalese market is based on European standards: 50 cycles, 220 volts. Professionals in the sector report that sophisticated medical equipment, such as imaging equipment, radiography and echography that use the standard u.s. 110 volts, is degraded when stepped-up to 220 volts. Further, all documentation and training need to be available in French. The availability of spare parts and a technically qualified agent to deliver after-sales service are critical to achieving success in the market.

The private sector market consists of private clinics and practices almost exclusively based in the Dakar area. This market segment does not have the same restrictions as the public sector, therefore used/ refurbished equipment could find acceptance here. However, the acceptance to date is somewhat limited. The importers contacted during this research mentioned that used equipment might have an image problem to overcome. The equipment is already perceived as old and there might be concern regarding its reliability and the availability of spare parts. Therefore, those importers rarely import used medical equipment. Some private purchases are done directly by the private clinics.

There are no government regulations barring the import of used medical equipment. As with other imports, used medical equipment is subject to import duties and taxes.

### *Key contacts*

#### *Government*

Ministry of Health Building Administratif Dakar
Tel: 221-821-50-48
Minister: Mr. Abdou Fall
Agetip Boulevard
Djily Mbaye Dakar
Tel: 839-02-02
M. Maguette Wade, Director
Agetip is a world bank-funded agency. Agetip monitors public tenders for medical equipment.

#### *Major Importers*

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Fax: (221) 825-8183
Mobil: (221) 638-5338
E-Mail: Techserv@Telecomplus.Sn
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Dr. Sammy Hannouche, Director

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M. Ndongo Ndoye, Director.
Elam-Thomas

## Singapore

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 13 March 2001 (Confirmed as still valid, 4 March 2002)

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

There are no restrictions or tariffs levied on new or used medical equipment. Singapore is generally a free trade port and an open economy. However, a 3.0-percent goods and services tax (GST) is imposed on goods sold and services locally provided. Imports are subject to GST but payments are refundable on re-exports.

*Can public health institutions buy used or refurbished Medical devices?*

Yes, public health institutions can buy used and refurbished medical devices. However, the public hospitals prefer to purchase new medical devices.

*Is there a market for used of refurbished devices?*

The general view is that there is no market for used or refurbished medical devices for the Singapore market as the general preference is for new medical devices.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

As stated above, there is no market for refurbished products.

## Slovenia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 25 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

The regulations for the import of medical equipment are prescribed in the Official Gazette, issues 101/1999 and 82/2000. There are no special restrictions or tariffs that would apply to the imports of used medical equipment. The import regime is the same as it is for the import of new medical equipment.

*Can public health institutions buy used or refurbished medical devices?*

Public health institutions can buy used or refurbished, but do not choose to do so.

*Is there a market for used or refurbished medical devices?*

According to previous experiences of several U.S. companies trying to sell refurbished X-ray systems in the region about two years ago, there is (almost) no market in the country for the refurbished products. According to an industry source, the mentality of Slovenian doctors mentality is against refurbished products. Also, all hospitals are state-owned with the exception of a couple of recently built small medical sanatoriums for wealthy people.

## South Africa

General Market Condition: Restricted

### *Source:* Policy Statement issued by the South African Department of Health, Directorate of Radiation Control

***Requirements with regard to Application for a Licence to Sell any Listed Electromedical Product***
***Hazardous Substances Act, 1973 (Act 15 of 1973)***

The primary responsibility and concern of the Directorate: Radiation Control, as part of the Department of Health, is the **safety** of the South African public, and especially the safety of the patient where listed electromedical products are concerned. The aim of the Directorate: Radiation Control is to establish a situation where patients can have reasonable assurance that any listed electromedical product that is used in a medical application, complies with a set of **minimum requirements** with respect to safety and performance. In specifying these requirements it is the express intention of the Directorate: Radiation Control to see to it that an unbroken and effective **line of communication** between the manufacturer of a particular product and the end user of that product is established and maintained. **These minimum requirements apply to the sale of all listed electromedical products, i.e. new, refurbished, and other pre-owned**, and are as follows:

A dealer wishing to sell any listed electromedical product on the South African market has to apply for a licence in terms of the Hazardous Substances Act, 1973 (Act 15 of 1973) by submitting a completed application form for **each model** to the Directorate: Radiation Control;

**and**

i) In the case of **new** products:

At least one of the procedures mentioned under Annexure A must be followed. If the manufacturer is not represented directly in South Africa, a copy of the letter is required in which the manufacturer states that this particular dealer in South Africa, applying for a licence for sale, is an authorised agent of that manufacturer in South Africa.

ii) In the case of **refurbished** products:

A copy of the **letter** is required in which the refurbisher states that this particular dealer in South Africa, who is applying for a licence for sale, is an **authorised** agent of that refurbisher in South Africa.

a) **If** the dealer chooses to follow the **FDA 510(k) procedure** (see **Annexure A**), the following is required:

- Copy of the 510(k) letter covering the original product.
- Letter from the original manufacturer stating that the refurbisher has been authorised by the original manufacturer to carry out refurbishing of a particular model, and that the original manufacturer undertakes to supply the refurbisher with replacement parts, upgrades, service bulletins, and hazard reports pertaining to that particular model.
- Letter from the refurbisher stating that the refurbished product is assembled to and match the original manufacturer's specifications for that particular model.

b) **If** the local dealer chooses to follow the **EC Declaration of Conformity procedure** (see **Annexure A**), the following is required:

- Copy of the EC Declaration of Conformity by the **refurbisher** of that particular model, and a copy of the relevant certificate(s) issued by the Notified Body in terms of the Council Directives 93/42/EEC or 90/385/EEC.

c) In the case of all other **pre-owned** products:

**The importation of any pre-owned product that has not been refurbished is not permitted,** unless such a product is to be refurbished in South Africa and then offered for sale. In this case the requirements for refurbished products apply (see (ii) above). **Only** pre-owned products that were used **within** South Africa previously, can be resold by a dealer without having been refurbished.

A dealer wishing to sell any such pre-owned product in South Africa must comply with the following requirements **when applying for a licence to sell that product**:

- Submit a copy of the letter in which the original manufacturer undertakes to supply this particular dealer in South Africa with replacement parts, upgrades, and hazard reports pertaining to a particular model.
- Submit **for each unit sold** a copy of the document which verifies the date on which that unit was acquired as new. (This will be a condition of the licence for sale for a particular model).
- Obtain the full service record (i.e. since new) **of each unit sold**, preferably completed by the manufacturer or his/her authorised agent in South Africa, and pass this service record on to the purchaser of that particular unit. (This will be a condition of the licence for sale for a particular model).

## *Annexure A*

1. EC Declaration of Conformity procedure

A copy of the **manufacturer's Declaration of Conformity** is required in which it is stated that a particular model complies with all the applicable provisions (including the Essential Requirements in Annex I) of the Council Directive **93/42/EEC** [Medical Devices Directive (MDD)] or the Council Directive **90/385/EEC** [Active Implantable Medical Devices Directive (AIMD)]. The certificate issued by a Notified Body, designated as such by a Member State of the European Union, enables the manufacturer to draw up this **Declaration of Conformity** in which he/she solemnly states that the device complies with the provisions of the MDD 93/42/EEC or AIMD 90/385/EEC. A Copy of the relevant certificate issued by a Notified Body is required in addition to the manufacturer's Declaration of Conformity.

Compliance with the MDD 93/42/EEC has been compulsory for all medical devices sold within the European Union since 14 June 1998 (Norway, Iceland, Liechtenstein and Switzerland are not members of the EU). If, in the case of systems such as X-ray installations, all the individual components already bear CE marking in terms of MDD 93/42/EEC, the person placing such a system on the market shall draw up a declaration in which the mutual compatibility of the components are verified. If not, the system is treated as a new device and an EC Declaration of Conformity has to be drawn up for the system as a whole.

2. FDA 510(k) procedure

A copy is required of either the **510(k)** or **PMA** letter in which approval is given by the FDA to market a particular model in the USA. Thus, if an electromedical device is being sold within the USA, the manufacturer will have in his/her possession at least 510(k) letter from the FDA authorising the sale of that particular model. If a device is classified as Class III by the FDA, a PMA (Pre-market Approval) letter must be issued before such a device can be offered for sale in the USA.

According to the FDA the manufacturer is best qualified to determine if a proposed device change or modification would warrant submission of a new 510(k) notification. If a manufacturer decides not to submit a new 510(k) notification, a record has to be kept of the reasons for not doing so. In the case of a product that is listed in terms of the Hazardous Substances Act, 1973 a copy of the appropriate **existing** 510(k) is required as well as the document containing the **reason(s)** for not submitting a new 510(k).

## Schedule of Listed Electronic Products

***Hazardous Substances Act, No. 15 of 1973***
***Regulation No. R. 1302, 14 June 1991***

**1 Any electronic product generating X-rays or other ionizing beams, electrons, neutrons or other particle radiation, namely-**

1 any diagnostic X-ray unit, including medical, dental and veterinary units;

2 any therapeutic X-ray unit;

3 any X-ray unit used for industrial, research, educational, security or any other purposes;

4 any electron accelerator;

5 any heavy particle accelerator;

6 any neutron generator;

7 any electron microscope;

8 any visual display unit, including any television receiving apparatus and video display monitoring system, that employs a cathode ray tube with an accelerating voltage exceeding 15kV; and

9 any cold cathode gas discharge tube producing X-rays, including those for teaching of X-ray principles and high voltage switchgear.

**2 Any electronic product generating electromagnetic radiation in the ultraviolet region, namely**

1 any sunlamp designed for the tanning of the skin of a human being;

2 any therapeutic lamp;

3 any high-intensity mercury-vapour discharge lamp;

4 any intra-oral curing device; and

5 any ultraviolet A lamp, including 'black lights'.

**3 Any electronic product emitting coherent electromagnetic radiation produced by stimulated emission, namely all laser products that emit radiation in excess of 0,8 x 10-9 watt in the wavelength region up to and including 400 nm or that emit radiation in excess of 0,39 x 10-6 watt in the wavelength region greater than 400 nm.**

**4 Any electronic product emitting electromagnetic radiation in the infra-red region, namely -**

1 any industrial heating and drying lamp installation exceeding 200 watt; and

2 any medical heating lamp exceeding 200 watt.

**5 Any electronic product emitting microwaves, radio or low frequency electromagnetic radiation, namely-**

1 any microwave oven;

2 any microwave diathermy unit;

3 any shortwave diathermy unit;

4 any electrosurgical unit;

5 any neuro-muscular stimulator;

6 any medical magnetic stimulator;

7 any radio-frequency generating device, system or installation, including radars, generating a radio-frequency output exceeding 200 watt RMS;

8 any low power radio-frequency generating device, system or installation, including citizen band radios, land mobile transmitters, marine transmitters and two-way (walkie talkie) radios, where normal operation entails close proximity to the operator or third parties and generating a radio-frequency output exceeding 25 watt RMS;

9 any microwave generating device, system or installation, including radars, generating a microwave output exceeding 400 watt RMS ;

10 any radio-frequency sealer;

11 any magnetic resonance imaging device; and

12 any blood warmer.

**6 Any electronic product emitting ultrasonic vibrations, namely-**

1 any diagnostic ultrasound appliance;

2 any therapeutic ultrasound appliance;

3 any surgical ultrasound appliance;

4 any lithotripsy appliance; and

5 any pest and rodent control appliance.

**7 Any electronic product used for medical, dental or veterinary applications employing radio-active nuclides, namely -**

1 any gamma camera;

2 any whole body counter;

3 any positron emission tomography scanner;

4 any linear scanner; and

5 any single photon emission computed tomograph (SPECT).

**8 Any high risk electronic product used for medical or dental applications, namely -**

1 any intra-aortic balloon pump;

2 any electronically controlled ventilator;

3 any electronically controlled anaesthetic machine;

4 any cardiac pacemaker;

5 any intra-cardiac electro- and phono-cardiographic monitor;

6 any electroconvulsive therapy unit;

7 any photocoagulator;

8 any infusion pump;

9 any syringe pump;

10 any infant incubator;

11 any infant transport incubator;

12 any hyperbaric therapy chamber;

13 any hemodialysis device;

14 any peritoneal dialysis machine;

15 any heart-lung bypass (perfusion) device;

16 any shockwave lithotripsy device;

17 any autotransfusion device;

18 any high pressure injection device;

19 any cryosurgical device; and

20 any transcutaneous O2/CO2 monitor.

**9 Any medium risk electronic product used for medical or dental applications, namely -**

1 any audiometer;

2 any ambulatory electrocardiographic recorder;

3 any electrocardiograph;

4 any electroencephalograph;

5 any electromyograph;

6 any cardiac catheterisation laboratory system;

7 any physiological monitor (ECG, pressure, respiration, temperature);

8 any phonocardiograph;

any non-invasive bloodpressure monitor;

any cardiac output computer;

any plethysmograph;

any evoked response device;

any pulmonary function analyser;

any bloodgas analyser;

any infusion controller;

any interferential device;

any capnograph; and

any diagnostic exercise device, including treadmill and cycle ergometers.

# Spain

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

## *Source:* Report from CS Post (via E-Mail) 11 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical Equipment?*

No.

*Can Public Health Institutions buy used or refurbished medical devices?*

Yes.

*Is there a market for used or refurbished medical devices?*

No. Both private and public health Institutions require new medical devices.

## Industry Sector Analysis, *Prosthesis/Trauma*, 10 October 2001

Representing 31 percent of total imports (USD 500 million), the United States is Spain's main supplier. U.S. medical equipment is highly regarded by Spanish doctors, domestic importers, and distributors, which consider the U.S. the world leader in this field. The growth in U.S. imports is estimated at 10 percent annually for the next two years. In peseta terms Spanish purchases from the United States have grown 43 percent from 1998-2000. This import figure is only for new equipment. Refurbished medical equipment is allowed to be imported in Spain, but both the public and private medical providers in Spain want only new equipment.

# Sri Lanka

General Market Condition: No Restrictions, but Government Healthcare Sector Can Not Buy

### *Source:* Report from CS Post (via E-Mail) 31 March 2002

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

Medical equipment is imported duty free into Sri Lanka. There is no special tariff in the case of used or refurbished medical equipment.

*Can public health institutions buy used or refurbished medical devices?*

Public Health Institutions are prohibited from buying used or refurbished equipment. The Government health sector is required to purchase only brand new medical equipment.

*Is there a market for used or refurbished devices?*

According to medical industry sources top private hospitals and medical service providers are not in favor of purchasing used medical equipment. Private medical equipment companies are also not keen to import used/refurbished medical equipment. The key factor is the inability of foreign suppliers of used equipment to provide after sales services, parts and manufacturers' warranties. However, they see limited prospects for used medical equipment, from smaller hospitals and medical clinics.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

Small hospitals, medical and dental clinics may require refurbished dental equipment, and other medical equipment ranging from ECG machines to ultra sound scanners. Well-known U.S. brands would have acceptance in the local market, if refurbished and supplied by the manufacturer. There is little or no demand for used medical equipment supplied by third parties. The key factors would be competitive prices compared to brand new equipment and efficient and comprehensive after sales service.

# Sweden

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

### *Source:* Report from CS Post (via E-Mail) 31 March 2000 (Confirmed as still accurate, 26 March 2002)

There are no special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment. (The CE mark required on all medical equipment marketed in Sweden). According to trade association there is no market for used or refurbished medical equipment. When replacing outdated medical equipment the public health institutions prefer to purchase new equipment.

## Switzerland

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via E-Mail) 13 March 2001 (Confirmed as still accurate 4 March 2002)

Switzerland is a small, highly developed and affluent market. It maintains one of the best health care systems in the world. Therefore importation of used medical equipment is practically non-existent. As a matter of fact, hospitals and doctors donate their used medical equipment/furniture to third world countries.

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

The same tariff rates apply to used medical equipment as to new ones.

*Can public health institutions buy used or refurbished Medical devices?*

Public health institutions can buy used equipment, however, is practically never done.

*Is there a market for used of refurbished devices?*

No. The market is practically non-existent.

## Syria

General Market Condition: Prohibited

### *Source:* Report from CS Post (via Cable) 17 February 2000 (Confirmed as still valid, 5 March 2002)

Syrian regulations prohibit the importation of used or refurbished medical equipment. The import licenses for medical equipment issued by the Ministry of Economy and Foreign Trade require the importer to acknowledge that the medical equipment being purchased is 'new equipment and not refurbished.'

## Taiwan

General Market Condition: No Restrictions

### *Source:* ISA Medical Electro-Diagnostic Apparatus 1 December 1999 (Confirmed as still accurate 28 March 2002)

***U.S. Market Position***

The market for used or refurbished medical devices is virtually nonexistent in Taiwan. Local hospitals prefer to buy new equipment and their budgets currently permit them to do so. Apart from the normal medical device registration, used equipment will likely face difficult market challenges in Taiwan.

### *Source:* Report from CS Post (via Cable) 27 July 1998 (Confirmed as still accurate 28 March 2002)

The importation of the following categories of used equipment is restricted in Taiwan: cars; equipment and parts used in the aerospace industry; equipment and parts used in ships and vessels; and generators and compressors with diesel engines. All other imports are treated the same as new

## Tanzania

General Market Condition: No Restrictions, but Public Institutions Can Not Buy

### *Source:* Report from CS Post (via E-Mail) 15 March 2002

Tanzania is pursuing a very flexible import administration regime on used and refurbished equipment in general. According to the East African Customs and Transfer Tax Management Act of 1952 Revised 1970 as applied by Act Number 19 of 1977 Section 14 and 15, there is no import restriction on used equipment in Tanzania.

However, on consignment basis, importation of used equipment into Tanzania is subject to inspection, verification and certification on its usability, suitability and appropriateness as governed by the Standards administered by the Tanzania Bureau of Standards (TBS) and any other Law. This is mostly applicable to items in the sensitive sectors that affect health and security.

Several industrial sectors have licensing and inspection boards. For instance, the National Medical and Pharmaceutical Board, under the Ministry of Health, handles medical equipment whereas Tanzania Bureau of Standards (TBS), under the Ministry of Industry and Trade, is charged with the administration of standards issues including 572 published standards. TBS is a member of the International Organization for Standards (ISO) and has been notified to the WTO as the contact point for issues related to the Agreement on Technical Barriers. Most Tanzanian standards are voluntary in nature and TBS adopts international standards whenever they exist. Sanitary and phytosanitary standards are the responsibility of the Ministry of Agriculture and Food Security (MAFS), which conducts an inspection and certification program for all imports of plant and animal products.

Motor vehicles of Japanese origin, continue to be the largest single group of used/reconditioned imported items into the country. The reforms that Tanzania has undertaken since 1985-and at a more accelerated pace in the past few years-have resulted in a trade policy framework that has been significantly liberalized and that is essentially based on tariffs. Liberalization of trade increased the volume of used equipment imported in other industrial sectors as well, especially office equipment (computers) and domestic appliances. Used items from various industrial sectors have been imported mostly through the free ports of the Middle East, South East Asia, Europe and South Africa. The United States of America continues to have negligible direct share of this trade in Tanzania despite the fact that some of the imported equipment is of U.S. origin.

Imports of used or refurbished equipment are receiving similar treatment as new ones. The whole scope of commercial goods being imported into Tanzania is subject to the same system of valuing goods for customs purposes which is fair, uniform, neutral and conforms to commercial realities.

Tanzania is implementing WTO Agreements including the Agreement on Customs Valuation (ACV). The procedure for valuation of goods for taxation purpose that is now in use is known as ‘Agreement on Customs Valuation (ACV) ‘. ACV prohibits the use of arbitrary or fictitious

Customs values. Pre-Shipment Inspection (PSI) is applied to goods of a value of above US Dollars Five Thousand ($ 5,000). Since duties are mainly levied on an ad valorem basis (based on value), a common problem is evaluating the equipment's current worth. Often, importers have been blamed, by the customs department, for under invoicing. In such cases, depreciation of the equipment had to be re-evaluated by the customs in collaboration with local dealers of the subjected item before an appropriate duty could be levied.

The recent reform of Tanzania's customs duties (customs tariff structure) has resulted in a simplified four-tier structure with tariff rates of 0 percent, 10 percent, 15 percent and 25 percent in that order. Pharmaceuticals and medicaments, motor vehicles in CKD form and inputs for manufacturing pharmaceutical products, raw materials, capital goods and replacement parts fall under zero tariff.

There is no absolute ban on the import of any type of used equipment to Tanzania. There is a market for used or refurbished medical equipment in Tanzania. Used hospital/medical equipment has to attain the approval of the National Medical and Pharmaceutical Board. Used X-ray machines are not recommended. Used dental and medical laboratory equipment are in the greatest demand. Neither public health institutions ror the Government of Tanzania can buy used or refurbished medical devices. Nuclear substance processing equipment requires an approval from the Commission on Atomic Power within the Tanzania Commission of Science and Technology.

Importation of used / refurbished equipment is growing fast in Tanzania. Motor vehicles of all ranges, tractors, television sets, computers, VCRs, refrigerators, cookers, photocopiers, sewing machines, hair dressing equipment, retread and used tires, used construction equipment, generators and engine parts, are some of the most notable used imported items. Japan has been leading in the export of reconditioned cars, which account for more than 75 perent of the value of the imported equipment. Germany, Sweden, United Kingdom, Italy, the Middle East, Denmark, Australia and South Africa are the main source of used domestic, industrial, construction and office equipment. These four industrial sectors are prospects for U.S. suppliers in Tanzania.

## Thailand

General Market Condition: Prohibited

### *Source:* Report from CS Post (via Cable) 21 March 2002

The Government of Thailand prohibits the importation of used or refurbished medical equipment into the country, but does not prohibit sales of those devices.

The potential market for refurbished devices is strong, especially for non-invasive, non-life-threatening devices. They include pulse oximeters, bedside monitoring devices, and blood pressure-monitoring devices.

### *Source:* Industry Sector Analysis, *Healthcare Products*, 8 March 2002

The Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health, controls importation of medical devices into Thailand. Prior approval of importation and device registration through this office is required. Any devices that are not allowed to be marketed or sold in the manufacturing country will not receive permission to be registered in, or imported into Thailand. The Thai Government does not allow importation of used or refurbished medical equipment.

### *Source:* Report from CS Post (via E-Mail) 1 April 2001 (Confirmed as still accurate, 21 March 2002)

The Government of Thailand prohibits the importation of used or refurbished medical equipment into the country, but does not prohibit sales of those devices. Public health institutions have a policy that prohibits the purchase of used or refurbished devices because of concerns about quality and reliability.

On the other hand, there is a market for refurbished devices among private health institutions, specifically non-invasive, non-life-threatening devices. The devices in this group include pulse oximeters, blood pressure monitoring devices, and other bedside monitoring devices. These devices are traded locally among the private health institutions. There is also a good potential for sales of device calibration services to both public and private hospitals in Thailand.

## Trinidad & Tobago

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 28 March 2002

There are no special restrictions or tarriffs that apply to used medical equipment that do not apply to new medical equiment. Duties are charged based on the cost of the product. Documentary evidence of cost is required. Public health institutions seldom buy used or refurbished medical devices. The market for used or refurbished medical devices is very small.

## Tunisia

General Market Condition: No Restrictions

### *Source:* Report from CS Post (via Cable) 30 October 1998 (Confirmed as still valid, 4 March 2002)

According to the Tunisian Ministry of Commerce, there are no statutory prohibitions on the import of used/refurbished equipment. Imports of used equipment are subject to strict control by the Ministry of Industry, whose inspectors verify the proper functioning of all used equipment imports.

There are no specific restrictions on individual categories of used/refurbished equipment, but each import is reviewed thoroughly and is admitted entry on a case-by-case basis.

While regulations are minimal, importation of used equipment into Tunisia is difficult as there is a strong preference for guarantees and after-sale service which comes with new equipment. Local banks that finance industrial products normally require that purchased equipment be new. Used equipment is sometimes imported as part of a foreign investor's contribution-in-kind to the capital of a project. The purchase of used equipment for government-funded projects is permitted only in exceptional circumstances.

The United States is Tunisia's fourth largest foreign supplier and U.S. technology is held in high regard in Tunisia for its state-of-the-art technology. Given the difficulty of assessing the true ease of entry for used equipment and the general Tunisian preference for new items, however, the Tunisian market is not particularly well suited for used/refurbished U.S. equipment exports.

# Turkey

General Market Condition: Restricted

## *Source:* Turkey Country Commercial Guide FY 2002

***Leading Sectors For US Exports And Investments***
***Name of Sector: Medical Equipment***
***ITA Industry Code: MED***

Turkey's demand for medical products and related equipment is expected to continue to grow in the coming years. The current total market size for the overall medical equipment sector is approximately US$ 750 million, with the U.S. share being a healthy fifteen percent. The estimated annual growth rate of imports from the United States is 20 percent.

In recent years, the Government of Turkey has allocated more funding to healthcare, substantially improving most of Turkey's healthcare standards. However, healthcare services are still inadequate to cope with a rapidly expanding population (currently about 65 million and growing by nearly two percent annually). Health expenditures represent approximately 5 percent of GNP.

The Turkish Ministry of Health (MOH) is the largest provider of healthcare in Turkey. Health care facilities operated by MOH account for approximately 84,000 beds. Other government agencies including the Ministry of National Defense, Social Security Agency (SSK), various public sector medical faculties and municipalities account for an additional 70,000 beds. The private sector, including foreign organizations and various associations, operate a total of 15,000 beds.

The private sector is actively expanding its role in the health sector. New capital-intensive medical technologies, such as magnetic resonance imaging (MRI), computed tomography (CT), and megavolt radiation therapy will continue to be purchased by Turkish hospitals. Major suppliers are the United States, Europe, and Japan. The Turkish business community has a high opinion of U.S. medical equipment and suppliers.

Demand for used, refurbished equipment (traditionally low), has increased over the last few years and is becoming an alternative source for emerging distributors and end-users because of lower prices and shorter delivery time. Current Turkish import regulations permit the importation of used equipment, no more than five years old. Equipment between five and ten years old is technically subject to a 50 percent import duty. The importation of devices over ten years old is prohibited.

The World Bank contributes to the financing of the government's healthcare improvement projects and has lent $76 million and $140 million respectively for the First and Second Health Projects between 1991 and 2001. Total investment required for these two projects was $346 million, and the Turkish Government supplied the remaining portion.

Most major government tenders outside the scope of the World Bank Health Project still require supplier credit. The GOT also encourages use of the 'Build-Operate-Transfer' (BOT) model as a means of procuring equipment for which funds are scarce. The BOT model calls for the vendor to install and operate the equipment, receive the revenues from the use of equipment, and finally transfer the equipment at the end of a specified period that covers expenses and profit.

Effective June 1, 1996, all medical equipment imports are subject to the Turkish Standards Institute (TSE) approval. USFDA approval is regarded as a seal of quality. Medical devices for sale (without restrictions) in the United States may normally be imported for sale in Turkey.

# Turkmenistan

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via Cable) 29 March 2000

So far, the government of Turkmenistan (GOTX) has introduced no rules regulating import of used and/or refurbished medical equipment in Turkmenistan. Import of such medical equipment is treated the same way as import of new equipment.

U.S. companies that plan importing used and/or refurbished medical equipment to Turkmenistan should be alert when a contract is negotiated. It should be clarified in the contract that import of used and/or refurbished medical equipment is agreed to by all parties participating in a transaction. Otherwise, a dispute with regard to the quality of imported equipment may arise. There have been such claims in the past.

So far, there have been no excise taxes or customs tariffs charged for imported used and/or refurbished medical equipment. Moreover, the customs and the state commodity and raw materials exchange do not charge service fees from those trade contracts where medical equipment is a part of a transaction. The main obstacle for U.S. companies planning to sell medical equipment in Turkmenistan is the non-convertibility of the Turkmen currency; hard currency is rationed, and importers must justify to the government their need for hard currency to pay for the goods they import.

The Turkmen market with a population of five million is relatively small and underdeveloped in terms of medical equipment supplies as well as medical personnel training and management. Needs are substantial, but means are limited. There is no medical equipment production in Turkmenistan and a potential market for used medical equipment does and will continue to exist here. So far, the GOTX has built a new pharmaceutical plant with the involvement of Indian Government credit line and maintains operation of an out-of-date pharmaceutical production facility in Ashgabat. Nonetheless, the Turkmen market relies heavily on imported medical items and pharmaceuticals. There are no Turkmen private clinics and hospitals in the country except for a Turkish private hospital, which has been operating in Ashgabat since 1998. The GOTX will continue to be the main partner in any investment project in the health care sector for the next decade. The only privatization that has taken place has involved the creation of local private drugstores. The Ministry of Health Care and Medical Industry, which handles the state investment fund for health care sector development, is responsible for financing health care projects. According to the Ministry of Health Care and Medical Industry, the market demand for medical equipment is evaluated at US$ 50 million. However, this figure could be much higher providing the GOTX has sufficient hard currency reserves in the investment fund.

In order to import foreign medical equipment into Turkmenistan including used and refurbished, one must be licensed for importation by the state center for registration of imported medical equipment and approved by Turkmenmedtekhnika, a state company handling medical equipment use and importation. The state inspectorate 'Turkmenstandartlary' provides certification of the imported medical equipment. Other government approvals also apply.

# Ukraine

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via E-Mail) 30 March 2001

### *Summary*

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

There are no special restrictions or tariffs that apply to used medical equipment in Ukraine.

*Can public health institutions buy used or refurbished Medical devices?*

Public health institutions can buy used and refurbished medical equipment.

*Is there a market for used of refurbished devices?*

The market for used medical equipment is small in Ukraine - importers prefer to buy new equipment, although new equipment is more expensive.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

The demand for used equipment is to be identified on case-by-case basis.

There are no special provisions for the registration of used or refurbished medical equipment. It is referred to as modification of an equipment or device. Below is a general description of the procedure of registration of medical equipment in Ukraine.

The registration procedure and forms to be used, for medical equipment and medical use products was approved by the Ministry of Health of Ukraine, September 26, 2000. The procedure was registered with the Ministry of Justice of Ukraine on January 17, 2001, and is now law. The registration (re-registration) of medical use products in Ukraine is performed by the State Department of Quality Control, Safety and Manufacture of Medicinal and Medical Use Products.

### *Import Registration Requirements*

Registration is a requirement for the importation of medical products into Ukraine. The applicant must first submit an application (on the standard form provided, see below for information that is to be provided on this form) for registration to the State Department on Control of Quality, Safety and Manufacture of Medicinal and Medical Use Products.

In addition the following must also be provided with the application: catalogues of the product, manuals, technical specifications, certificates (manufacturer's certificate, certificate of origin), foreign certificates (if available), a certificate of conformance issued by a Ukrainian certifying agency (if available), information on manufacturing standards (if available), trade mark samples, manufacturer's registration documents.

Registration is performed by the State Department on Control of Quality, Safety and Manufacture of Medicinal and Medical Use Products, and is based on evaluation of the product by the expert testing agencies. When registered, the product is included in the State register of medical equipment and medical use products.

Registration is valid for five years. The procedure for renewal of registration is the same, as described above.

### *Completing the Registration Form*

Companies registering medical devices will need to provide the following information on the registration form:

- Name of the medical use product (synonyms, trade mark (in original language, in English, and in Ukrainian).
- Applicant (country where the applicant is registered, address, phone, fax, e-mail, national registration number and code).
- Manufacturer (country where the manufacturer is registered, address, phone, fax, e-mail, national registration number).
- Document confirming the authority of an applicant to represent a manufacturer (if an applicant is not a manufacturer - a contract, power of attorney).
- Ukrainian customs code of the medical use product.
- A certificate of conformance issued by a Ukrainian certifying agency.
- A signed statement that the 'product complies with quality and safety requirements, stated in the supporting documentation, and requirements of the Ukrainian legislation as to quality, and safety for human health and environment.

The documents that confirm the compliance of goods to Ukrainian certification requirements are:

- A certificate of conformance issued by a Ukrainian certifying agency, upon certification of goods; or
- A certificate of acceptance of a foreign certificate issued by a Ukrainian certifying agency, upon acceptance of a foreign certificate.

Note: Certificates issued by foreign authorities are recognized in Ukraine only to the extent provided in international treaties to which Ukraine is a party. No intergovernmental agreements on goods certification exist between Ukraine and the U.S. and a certificate of acceptance of a foreign certificate may not be issued without the actual testing of the product.

### *Contacts in the Ukrainian State Department on Control of Quality, Safety and Manufacture of Medicinal and Medical Use Products:*

Division for Registration and Certification of Medical Equipment and Medical Use Products
Yaroslav Penishkevich, Head of the Division
50 Popudrenko St.
Kiev 253660
Ukraine

Tel: (380-44) 559-5033
Fax: (380-44) 513-7214
E-Mail: yary@cmt.kiev.ua

## *Source:* ISA Medical and Clinical Laboratory Equipment 1 June 2000

Equipment used in public hospitals is typically obsolete and/or worn-out. Given the financial condition of many health institutions, replacement will be slow or non-existent. The needs are extensive (particularly, in laboratory equipment), but financing remains the major difficulty.

The desire for used laboratory equipment is average. But a potential market for used equipment does exists; the preferred approach includes the creation of a refurbishing joint venture with a local partner.

## United Arab Emirates

No Restrictions but Permission of Ministry of Health Required

### *Source:* Report from CS Post (via E-Mail) 29 April 2001 (Confirmed as still accurate 15 April 2002)

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

Used medical equipment are levied the same custom charges as new medical equipment. The charges are 4 percent.

*Can public health institutions buy used or refurbished Medical devices?*

Public health institutions do not buy used or refurbished medical devices according to a government regulation.

*Is there a market for used of refurbished devices?*

The government in the UAE is the main health care provider. Government healthcare services account for 80 percent of the market. Only 20 percent of the market for health care services is supplied by private clinics and hospitals. The majority of the bigger private clinics and hospitals prefer new equipment. It could thus be well said that the market for refurbished medical equipment in the UAE is small.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

Smaller private clinics and hospitals buy refurbished imaging, diagnostic, radiology, and ultrasound equipment.

### *Source:* Report from CS Post (via Cable) 12 August 1998

The United Arab Emirates (U.A.E.) imposes no restrictions on the import of used or refurbished equipment. Importers of such items should have this activity stated in their company's registration at the Ministry of Economy and at the Chamber of Commerce and Industry in the emirate in which they are operating. The import of used/refurbished medical, telecommunications, and military equipment is subject to permission of the respective ministry. Usually the import of new or used/refurbished equipment in these categories is done under the terms of government tender specifications. The import of refurbished or used equipment in violation of the tender specifications will be denied permission by the tendering party.

A flat customs tariff rate of 4 percent on the total invoice value applies to the import of new as well as used/refurbished equipment.

As per U.A.E. law, if an agency for a specified product/equipment is registered with the Ministry of Economy and Commerce, then the right to import that product is restricted to the registered agent.

# United Kingdom

General Market Condition: No Restrictions, but CE Mark is Required
*See also entry for the European Union.*

## *Source:* Report from CS Post (via E-Mail) 22 March 2002

The United Kingdom has a growing requirement and interest for used medical equipment, across all sectors. The majority of such purchases are made by hospitals that are part of the United Kingdom's government-funded National Health Service (NHS). Such pre-owned equipment is subject to the same import duties and regulations as new devices.

The U.K. medical equipment market is driven by the NHS—the United Kingdom's universal, publicly funded healthcare system—which accounts for about 85 percent of total U.K. healthcare provision. As such, the NHS accounts for the majority of medical equipment purchases in the $3-billion U.K. market.

In the past, NHS purchases of used medical equipment have focused on radiology equipment such as X-ray machines and scanners. Currently, NHS demand covers all sectors: large surgical equipment, radiology equipment and other medical diagnostic equipment. Given the NHS' recent moves to improve the standard of care for cancer patients, the market for all pre-owned diagnostic medical equipment should increase.

The majority of used medical equipment procured by the NHS is purchased by individual hospital trusts, which are regional groupings of the 1,578 NHS hospitals. Contact information for these trusts can be found at www.doh.gov.uk.

The NHS also has a central purchasing organization—the NHS purchasing and supplies agency—(www.pasa.doh.gov.uk) that influences more than half of the NHS' total spend on supplies. Although NHS hospitals are not required to purchase from this agency, over 98 percent of NHS trusts place all, most, or some of their business with the organization. Contacts at this agency report that in the past they have done little procurement of used medical equipment but have recently been approached by a U.S. company who sells pre-owned medical equipment and was very interested in exploring similar opportunities. Senior buyers at PASA told us that they were there certainly was an important niche for pre-owned medical equipment in the UK market. The NHS purchasing and supplies agency can be reached on 44-1244-586-859.

In addition, over the next three years, the NHS will be purchasing $150-million worth of new cancer equipment—including diagnostic equipment, linear accelerators, and breast screening equipment—for over 200 hospitals. The purchases will be funded by the U.K. National Lottery's New Opportunities Fund (NOF), contact information for which can be found on the website www.noh.org.uk.

Private sector procurement of medical equipment is financed by the individual organization or hospital group. There are currently 229 private hospitals in the United Kingdom, and these organizations purchase very limited amounts of used equipment, if any at all. Information on the U.K. private healthcare sector can be found on the website www.iha.org.uk.

Any used or refurbished medical equipment sold in the U.K. market faces the same restrictions and regulations as new equipment. As with a new medical device, a used or refurbished medical device must obtain a CE mark that enables the product to be marketed anywhere within the EU. To obtain a CE mark, full compliance with the appropriate EU directive must be achieved. The three main EU medical devices directives are the EU Medical Devices Directive, the Active Implantable Medical Devices Directive, and the EU In-Vitro Diagnostic Medical Devices Directive (to be fully implemented in December 2005).

If a product has obtained a CE mark and is then refurbished, no re-registering is required if the product is refurbished with original equivalent parts (i.e. parts must meet manufacturer specifications). If significant alterations occur, previous regulatory approval could be invalidated.

Within the United Kingdom, the U.K. Medical Devices Agency (MDA) enforces regulations and deals with inquiries concerning compliance to the EU directives. Information about the MDA and full descriptions of the EU directives can be obtained on the Webster www.mca.gov.uk

Used or refurbished medical equipment is subject to the same import duties as new devices. The majority of medical equipment is classified into one of two categories in the Harmonized Tariff Schedule (HTS): HTS 9018 (medical, surgical, and dental instruments and apparatus) and HTS 9402 (medical, surgical, and dental furniture). New or used medical equipment classified under HTS 9018 and 9402 can be imported into the United Kingdom duty-free. A 17.5 percent value-added tax (VAT) is levied on the CIF value of the products (the value of the product, plus carriage, insurance, and freight).

## Uruguay

General Market Condition: Restricted

### *Source:* Report from CS Post (via E-Mail) 28 March 2001 (confirmed as still accurate 21 March 2002)

Unfortunately there would appear to be no niche for used medical equipment in the Uruguayan market. Tariffs on used items are applied on the value if new! Moreover, as a member of Mercosur, Uruguay applies a common external tariff to products coming from outside Mercosur. The common external tariff in some cases is as high as 16.5 percent, whereas the tariff on medical equipment coming from the other Mercosur countries is zero percent.

Although the same regulations apply to used equipment as to new equipment, the Ministry of Public Health tends to make the procedures extremely troublesome (even in the case of donations!), so local importers do not look for used equipment. The Ministry of Public Health will accept used equipment as donations only and they make it difficult for themselves also!

Local costs for repairing/refurbishing are low with high skills. So when upgrading, high-end institutions/users tend to sell their equipment to those with lower technologies and they can then have it as new at low costs.

## Uzbekistan

General Market Condition: Restricted

### *Source:* International Market Insight, *Import Regulations for Medical Equipment in Uzbekistan,* 2 April 2002

#### *Summary*

The act of registering or re-registering of products for medical use in Uzbekistan is performed by the Head Department of the Drug and Medical Equipment Quality Control (HDDMEQC), Public Health Ministry of the Republic of Uzbekistan.

The procedures for registering medical equipment and related products were issued by the Cabinet of Ministers of Uzbekistan on May 25, 1995 and then were approved by the Ministry of Health.

Registration is a requirement for the importation of medical products into Uzbekistan. Once registered, a product is included in the State register of medical equipment and medical related products.

Registration is valid for five years.

### *Medical Equipment and supplies Regisration Process*

To import medical equipment and supplies, companies must register said equipment with the Head Department of drug and medical equipment quality control. A complete set of documents must be submitted to the Head Department of Drug and Medical Equipment Quality Control for registration. The length of the registration period depends on the type of equipment or medical supply. The company must submit 2 copies of all documents in English and in Russian.

1. Application form are distributed by the Committee on new medical technology of HDDMEQC; the form contains questions regarding the applicant-firm, country of origin; type of manufacturing firm, method of manufacturing; organizational structure standard package;
2. General information about equipment or supplies;
3. Certificate on the equipment production under the GMP (good manufacturing practice) conditions or other international standard requirements (original or notarized copy);
4. Certificate on medical equipment registration with the national certification system (original or notarized copy);
5. Instruction on administration and (or) technical passport;
6. Clinical testing reports;
7. Technical documentation on the medical equipment must have the information in the conformity of the equipment with the international standards;
8. Testing methods and procedures description of the medical equipment;
9. Information on the guarantee period of the equipment;
10. Technical description of main parts, electric lines, requirements to supplies, maintenance, water and energy supply;
11. Copies of equipment or supplies administration in hospitals or clinics (by the mail literature publications);
12. Samples of the medical equipment or medical supplies.

When applying for registration a company must also attach a certificate from a local bank, confirming payment of the appropriate fee, which is determined on the types of equipment. Minimal fee is about US$500.

Once all papers are submitted and the appropriate fee paid, pharmaceuticals are then passed over to Uzbekistan hospitals that will do all clinical testing. Registration process usually takes up to 6 months.

When medical equipment or supplies are registered, companies will receive registration certificates, which will be attached to the contract.

### *Regulations for Used Medical Equipment*

Medical equipment that has been in use may not be registered in the Republic of Uzbekistan. However, there is a need to point out that medical equipment imported to the territory of Uzbekistan should pass the governmental certification, except equipment, which was produced before 1995.Use of the former exploited medical technology in the hospitals and testing institutions is possible only after passing the strict quality, suitability and security conditions in a technical evaluation with the technological experts from a special commission, created under HDDMEQC RU.

During the exploration period equipment is regularly checked by the departmental supervision.

Medical equipment, which is supplied through humanitarian aid can be distributed the final place of destination, only after certification testing.

### *Main Contact Information*

The package of standard forms can be obtained at the Receptionist Desk of Committee on new medical technology of the Head Department of Drug and Medical Equipment Quality Control at the address below.

More information can be obtained from:

Mr. Abdunamon Sidikov
Head of the External Economic Activities Department Ministry of Health of Uzbekistan
12 Navoi street,
Tashkent 700011, Uzbekistan
Tel: (998) 712 68 26 32, 68 08 11
Fax: (998) 712 68 06 41

Mr. Akhmat Yunuskhojaev
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Ministry of Health of Uzbekistan
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Ms. Tyrena Holley, Senior Commercial Officer
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Tashkent 700000 Uzbekistan

**U.S. mailing address:**
Commercial Service
Department of State
7110 Tashkent Place
Washington, DC 20521-7110

# Venezuela

General Market Condition: No Restrictions, but Government Agencies do not Buy

## *Source:* Report from CS Post (via E-Mail) 22 May 2001

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

There are no restrictions or special tariffs for used medical equipment. The same import duties apply for new and for used equipment.

*Can public health institutions buy used or refurbished medical devices?*

There are no prohibitions but as a rule the Venezuelan Government agencies will not buy used or refurbished equipment of any type.

## *Source:* ISA Medical 1 September 2000

Overall hospitals in Venezuela are not managed efficiently according to industry analysts. Therefore it has been difficult to build up a reserve fund for future technology upgrades and acquisitions. The same doctors work in both the public and the private sectors. However, in the public sector the government does not provide adequate tools and equipment, nor the proper infrastructure. This has been the situation over the past twenty years. In Caracas over the past ten years private hospitals were unable to make direct investments as they were greatly affected by the recession. Nevertheless, they managed to form strategic alliances with the medical distributors, which resulted in many private hospitals having the latest technology. Unfortunately this kind of initiative has not taken place in the rest of Venezuela.

Demand of medical equipment and supplies will be determined mainly by importers' purchasing power, product price and the rate of growth in the market of used equipment. Local statistics indicate that imports of refurbished equipment have grown approximately 60 percent over the past two years. This is the result of the continuous currency devaluation, the limited access to import new equipment, increased health costs and patient's diminishing purchasing power. The demand for U.S. refurbished equipment is becoming an alternative source for distributors and end users, as long as technical support and service are available.

There is a need in the public health sector for high technology equipment, such as tomographers, ophthalmologic and optical instruments, cobalt pumps (nuclear medicine), magnetic resonance chambers, X-ray apparatus, laboratory and hematology testing equipment, infusion and transfusion equipment, cancer diagnostic and therapy equipment, hemodialysis equipment,

electrocardiographs, electroencephalographs, linear accelerators, equipment for heart disease, apparatus for intensive care units and dental equipment.

# Vietnam

General Market Condition: Restricted

## *Source:* Industry Sector Analysis, Medical Diagnostic Equipment, 31 January 2002

The Government has recognized that neither the State budget nor even the largesse of official development assistance (ODA) donors can cope with Vietnam's needs for investment in health care facilities, and over the past few years has promulgated measures to encourage private investment in this sector, which was previously reserved for the State. Although private hospitals only serve a limited market of wealthier Vietnamese and some foreign nationals, the number of private hospitals grew from 6 in 1999 to 10 in 2000, each with around US$2 miilion in invested capital. Private hospitals are more open to purchasing new equipment and employing advanced techniques that will allow them to differentiate themselves in the market.

Supplementing hospitals, the system also has 19,836 private health care clinics (many run as 'sidelines' by staff doctors from State-owned hospitals), 7,015 traditional medicine centers, 3,432 specialized clinics, and 550 family-run clinics. These establishments are predominately small-scale and are not likely to procure much high-end equipment. However, they may represent a market for used equipment with service and warranty.

Regarding used equipment, Decision 2019/1997/QD-BKHCNMT dated December 1, 1997, stipulates that the Ministry of Science, Technology, and Environment (MOSTE) must inspect imported used medical equipment. Imported used medical equipment must retain at least 80 percent of its life expectancy and must not consume more than 10 percent of fuels or electricity used by newer versions of the equipment.

## *Source:* ISA Medical 1 January 2001

### *Import Climate*

Importation of medical equipment into Vietnam must go through a trading company that has an import license. In the past, only state-own enterprises had licenses to import medical equipment to Vietnam, and these trading companies charged the real equipment buyers or distributors a few percent commission rate on the total value of the imported goods. Now, any business entity, including foreign invested enterprises that have a legally registered business license, can be engaged in direct import and export activities.

Decree 11/1999/ND-CP issued on 3 March 1999 stipulates the ban of medical equipment. Only medical equipment intended for sex enhancement and aphrodisiac purposes have been clearly identified as banned medical equipment. Decision 088/2000/QD/BTM issued 18/2/2000 provides further detailed instructions and a list of banned medical equipment.

According to the Government's Decree 89/CP promulgated on 12 December 1995, each year the Ministry of Health, in consultation with the Ministry of Trade, issues a list of equipment in which importation must be registered and approved by the Ministry of Health. Decree 89/CP has been altered many times and importation of medical equipment is now regulated by Decision 242/1999/QD/TTg issued on 30 December 1999. Decree 89/CP is now replaced by Circular 05/2000/TT-BTM issued 21 February 2000.

The current list for equipment needing to be registered and approved is detailed below:

- CT Scanner and gamma scanner;
- Cobalt and accelerator equipment;
- Simulator equipment;
- Magnetic resonance equipment;
- Blood filter/sterilizing equipment;
- Ultra-sound color Doppler equipment;
- X-ray equipment;
- Emergency/Recovery equipment;
- Laboratory equipment;
- Specialty equipment, i.e. obstetrician, pediatric, and optical equipment;
- Sterilizing equipment

Based on Decision 2019/1997/QD-BKHCNMT issued 1 December 1997, the Ministry of Science, Technology, and Environment must inspect imported used medical equipment. The Decision stipulates that imported used medical equipment must retain equal to or more than 80 percent of its life expectancy and must not consume more than 10 percent of fuels or electricity than newer versions of the equipment.

Import tax for medical equipment generally ranges from 0 percent to 5 percent, and the equipment is subjected to a value added tax. Effective as of 1 January 1999, a new value added tax was imposed on goods and services consumed in Vietnam. The standard VAT rate for medical equipment is 5 percent and a spare part is 10 percent. Unless otherwise approved by the Ministry of Finance, taxes are based upon the calendar year, regardless of a company's fiscal year. Medical equipment imported from countries that have bilateral trade agreements with Vietnam receive a preferential tax rate. Import taxes imposed on medical equipment are classified in Decision 172/TT-BTC issued on 22 December 1998.

In general, all importation procedures for medical equipment take about two to three weeks and there are no major difficulties during this process.

### *Labeling Requirement*

On August 30 1999, the Prime Minister promulgated Decision No. regarding the regulation for labeling of domestically circulated goods and imported/exported goods. According to this law, label affixation is required for medical equipment. The importer must provide information on the label that mentions the

- Name of the equipment;
- Name and address of traders responsible for the equipment, i.e., the importer in this case;
- Instructions on using, operating and preserving the equipment; and
- Origin of the equipment.

## ISA Medical 1 May 2000

Used equipment, that has been refurbished, has significant market potential in Vietnam, especially in the private Vietnamese clinic sector.

# Yemen

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via Cable) 27 March 2001

*Are there special restrictions or tariffs that apply to used equipment that do not apply to new medical equipment?*

> There are no restrictions on the importation of used equipment, except that it be in good condition. Tariff rates are lower for used equipment than for new equipment, and this applies to used medical equipment. The tariff on new medical equipment is five percent. The custom duties are exempted if the hospital is an investment project, but the used equipment must not be more than eight years old.

*Can public health institutions buy used or refurbished Medical devices?*

> Yes, public health institutions buy used or refurbished medical devices when priced competitively with new equipment. Yemen's Ministry of Health buys medical equipment through the tendering system.

*Is there a market for used of refurbished devices?*

> Yes, the market for used medical equipment is good, especially in private hospitals.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

> The greatest demand for refurbished medical equipment is from small hospitals, clinics and health centers.

Yemen's ministry of Public Health is unable to cope with increasing demand for modern health services, so it has encouraged the private sector to establish hospitals and clinics. Statistics indicate that Yemen has over 105 government hospitals, 200 private hospitals, over 750 health care centers and clinics, and 2,900 pharmacies, representing a significant market for medical instruments, supplies, and pharmaceuticals. Yemeni expatriates and businessmen are planning to invest in larger hospitals. More than 60 private companies are importing and trading in medical instruments, supplies, and pharmaceuticals.

## Report from CS Post (via Cable) 4 April 2000

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Public health institutions buy used or refurbished medical devices when priced competitively with new equipment. Yemen's Ministry of Health buys medical equipment through the tendering system.

The market for used medical equipment is good, especially in private hospitals.

Yemen has over 100 government hospitals, 550 small private hospitals and clinics and over 2,700 pharmacies, representing a significant market for medical instruments, supplies, and pharmaceuticals. More than 50 private companies are importing and trading in medical devices. With a population of 17.7 million that is growing at a 3.5 percent rate, the need for all types of equipment is great and will continue to grow.

# Zambia

General Market Condition: No Restrictions

## *Source:* Report from CS Post (via E-Mail) 1 March 2002

*Are there special restrictions or tariffs that apply to used medical equipment that do not apply to new medical equipment?*

No. There are no special restrictions or tariffs that apply to importation of used medical equipment that do not apply to new medical equipment.

*Can public health institutions buy used or refurbished medical devices?*

Yes. Public health institutions buy used or refurbished medical devices however, they depend on donations and purchases through donor funded projects. Public health institutions are under funded by the central government.

*Is there a market for used or refurbished medical devices?*

Yes. There is a huge market for used or refurbished medical devices.

*If there is a market, what types of used or refurbished medical equipment are in the greatest demand?*

There is a market for all types of used or refurbished medical equipment. There are no facilities for local manufacturing so all medical equipment is procured from abroad.

# Conclusions and Next Steps

Based on the summary of information contained in this report, it is clear that U.S. exporters of pre-owned (used and refurbished medical devices) face significant market restrictions above and beyond those faced by exporters of new medical devices. These additional restrictions take a variety of forms, but include the following:

- Outright ban;
- High tariffs or fees;
- Ban on the purchase of pre-owned equipment by public institutions;
- Requirements that after-sale service or technical support be provided;
- Prohibition on the importation of pre-owned equipment that has not been refurbished;
- Restrictions on the importation of equipment unless it has been refurbished by the original manufacturer or its authorized agent;
- Special certification requirements;
- Requirements for warranties;
- Restrictions on the age of equipment; and
- Ban on pre-owned equipment that competes with locally produced devices.

To a large degree, these restrictions that target pre-owned equipment exist for the following reasons:

- The problems that the importing countries have experienced with pre-owned equipment in the past;
- The perception that the lower cost of used equipment does not justify the risk that the devices may not perform as well as new ones;
- The concern that replacement parts or service may be difficult or impossible to obtain for pre-owned medical devices;
- The perception that refurbished medical devices will perform better than pre-owned equipment that has not been refurbished;
- The perception that medical devices refurbished by the original manufacturer will perform better than equipment refurbished by a firm that is not the original manufacturer;
- The perception that pre-owned medical devices are of lower technology and result in lower quality healthcare; and
- The concern that pre-owned equipment may pose safety risks since the U.S. market for pre-owned devices is largely unregulated and no FDA approval is generally required.

Some of these concerns and perceptions are valid and some are not, but each country has the right to establish its own policies regulating the types of pre-owned devices it is willing to accept and the terms under which it will do so. As long as all countries exporting products are treated equally and market access barriers do not violate any specific trade agreements, the restrictions are not likely to be successfully challenged.

The U.S. pre-owned equipment industry has several on-going activities that may improve the market for U.S. exports by addressing the concerns and perceptions listed above:

- One U.S. industry association, the International Association of Medical Equipment Remarketers and Servicers (IAMERS) has developed a code of ethics with which all members agree to comply. IAMERS responds to complaints against its members and on several occasions has removed member firms for failure to comply with its ethics code. IAMERS-associated firms, however, remain a small segment of the industry, and its membership is heavily dominated by firms focusing on the resale and servicing of imaging equipment.
- A joint effort of IAMERS, FDA, and several new-product industry associations—the Advanced Medical Technology Association (AdvaMed—formerly the Health Industry Manufacturers Associations—HIMA), National Electrical Manufacturers Associations (NEMA), and the Medical Device Manufacturers Association (MDMA)—has led to a draft agreement for self-regulation of the pre-owned medical device industry in 1999. (*See Appendix B*). Approval of the draft agreement by FDA is pending in Spring 2001.
- Several U.S. medical device original equipment manufacturers (OEMs) have established or are establishing units to buy back and remanufacture their own devices, which are then resold with a full warranty and service availability.
- Many U.S. pre-owned medical device firms are now offering some type of warranty with the products they sell.

An important development relating to the international trade in used and refurbished medical equipment occurred in May 2002. For the first time, refurbished medical equipment was the subject of a workshop at the Global Harmonization Task Force (GHTF) Conference.

The GHTF is a voluntary group of representatives from national medical-device regulatory authorities and the regulated industry. The GHTF is comprised of representatives from five founding members (Australia, Canada, the European Union, Japan, and the United States). The purpose of the GHTF is to encourage convergence in regulatory practices. The primary way in which this is accomplished is via the publication and dissemination of harmonized guidance documents on basic regulatory practices. The GHTF also serves as an information exchange forum through which countries with medical device regulatory systems under development can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

At the Ninth GHTF Conference, which took place in Singapore, May 12–16, 2002, a workshop focused on the "Regulation and Supply of Refurbished Medical Devices." Although no report was issued by the workshop, the session was important for bringing increased attention to refurbished medical devices. Copies of the presentations made at Ninth Conference, including those from the workship on refurbished medical devices, are available at the GHTF web site:

http://ghtf.org

In order to continue encouraging discussion of issues relating to the international trade in pre-owned medical devices, the Department of Commerce (DOC) will continue to update this report annually. We will continue to ask each DOC Foreign Commercial Service office to review the report as it relates to its country, checking it for accuracy and updating it as necessary. We are also requesting U.S. industry associations and firms involved with the sale of pre-owned medical devices to review this report and to inform us if their experience confirms or contradicts the information it contains.

# Appendix A
# Markets for Which No Information Was Available

For the listed markets, there were no relevant ISA or IMI reports discussing pre-owned equipment or import regulations for medical devices and the U.S. Foreign Commercial Service post in that country did not provide a response to OMMI's cable requesting information.

**Markets with No Available Information**

| | | | |
|---|---|---|---|
| Abu Dhabi | Comoros | Latvia | Qatar |
| Afghanistan | Congo (Brazzaville) | Lebanon | Rwanda |
| Albania | Congo (Kinshasa) | Lesotho | St. Kitts and Nevis |
| Algeria | Cote D'Ivoire | Libya | St. Lucia |
| Andorra | Cuba | Liechtenstein | St. Vincent & the Grenadines |
| Angola | Cyprus | Lithuania | Samoa |
| Antigua and Barbuda | Djibouti | Luxembourg * | San Marino |
| Armenia | Dominica | Macedonia | São Tome and Principe |
| Azerbaijan | Equatorial Guinea | Madagascar | Seychelles |
| Bahrain | Eritrea | Maldives | Sierra Leone |
| Bangladesh | Estonia | Mali | Slovakia |
| Belarus | Fiji | Malta | Solomon Islands |
| Benin | Gambia, The | Marshall Islands | Somalia |
| Bhutan | Georgia | Mauritania | Sudan |
| Bosnia and Herzegovina | Grenada | Mauritius | Suriname |
| Brunei | Guinea-Bissau | Micronesia | Swaziland |
| Bulgaria | Guyana | Monaco | Tajikistan |
| Burkina Faso | Iran | Mongolia | Togo |
| Burma | Iraq | Namibia | Tonga |
| Burundi | Ireland * | Nauru | Tuvalu |
| Cambodia | Kenya | Niger | Uganda |
| Cape Verde | Korea, North | Norway | Vanuatu |
| Central African Republic | Laos | Palau | Zimbabwe |

* Although specific information is lacking, general rules of the European Community apply.

*Source: U.S. Department of Commerce*

# Appendix B
# Proposed Voluntary Self-Regulation of the Pre-Owned Medical Device Industry

### *Background*

In 1999, a joint effort of the American Association of Medical Instrumentation (AAMI), the Emergency Care Research Institute (ECRI), the International Association of Medical Equipment Remarketers and Services (IAMERS), the U.S. Food and Drug Administration (FDA), and several new-product industry associations—the Advanced Medical Technology Association (AdvaMed—formerly the Health Industry Manufacturers Associations—HIMA), the National Electrical Manufacturers Associations (NEMA), and the Medical Device Manufacturers Association (MDMA)—led to a draft agreement for self-regulation of the pre-owned medical device industry. The proposed self-regulation includes voluntary labeling that tracks the pre-owned equipment, registration of medical device resellers, and mandatory FDA review of medical devices when original specifications are modified in any way. The draft agreement also foresees a system for distributing recall and hazard notices.

### *Status of the Proposal*

Approval of the draft agreement by FDA has been pending since Fall 1999. In June 2001, a spokesperson for the FDA indicated that review of the proposal was delayed by consideration of guidance for the re-use of single-use devices. Because the FDA desired to maintain a clear distinction between used capital equipment and re-use of single-use devices, the agency delayed consideration of the proposed self-regulatory system for pre-owned capital equipment until guidance had been issued on the re-use of single use devices.

On 14 August 2000, the FDA released a document entitled 'Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.' This document provides guidance to third-party and hospitals reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use. Issuance of that document has enabled the FDA to renew consideration of the voluntary regulatory system to pre-owned capital equipment.

According to the FDA spokesperson, the FDA does not intend to publish a regulation implementing the voluntary regulatory system, but rather to issue a Guidance Document explaining the application of the Food, Drug, and Cosmetic Act to remarketing and endorsing the voluntary proposal. As a first step, the FDA would encourage the organizations that originally drafted the proposal to move forward with establishing the third-party registry that would make hazard, recall, and safety-related service notices available to customers of participating re-sellers under the voluntary regulatory system.

As of May 2002, this proposed document had not issued, but a spokesperson indicated that it would be forthcoming later in the year.

### *Details of the Proposed Voluntary System of Self-Regulation*

Under this proposed voluntary system of self-regulation, the participating organizations would have labeled the used equipment they service or remarket with the following information:

- The name of the servicing or remarketing organization;
- A toll-free telephone number or other contact information for the organization;

- Service documentation describing the work performed using standard terminology (*see below*);
- The date the work was performed and/or the date the transaction was completed; and
- The appropriate Device Condition code (*see below*).

The proposed voluntary regulations defined 12 key terms relating to activities that could be undertaken as part of the equipment refurbishing process. The service documentation included on the label would have had to use this terminology. These terms included the following:

*Calibration*—is the checking and adjusting of a device's functions in a quantitative manner, to make those functions conform, within a specified tolerance to an identified standard.

*Cleaning*—is the removal of ordinary dirt or debris.

*Cosmetic Restoration*—is the restoration, or partial restoration, repair or replacement of any components of the device that do not have a direct effect on the device's functional performance or safety.

*Decontamination*—is the use of physical or chemical means to remove, inactivate, or destroy pathogenic organisms on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

*Installation*—is the setting of a device, or a hardware or software component of a device, into its proper position and making it ready for use according to the manufacturer's specification.

*Performance Verification*—is testing conducted to verify that the device functions properly and meets the performance specifications; such testing is normally conducted during the device's initial acceptance testing.

*Preventive Maintenance*—is the inspection, cleaning, lubricating, adjustment or replacement of a device's nondurable parts. Nondurable parts are those components of the device that have been identified either by the device manufacturer or by general industry experience as needing periodic attention, or being subject to functional deterioration and having a useful lifetime less than that of the complete device. Examples include filters, batteries, cables, bearings, gaskets, and flexible tubing.

*Remarketing*—is the act of facilitating the transfer of ownership of a medical device by sale, gift, or lease.

*Repair*—is the restoration of the device to its original level of functional performance and safety after it has malfunctioned or sustained damage.

*Safety Testing*—is testing conducted to verify that the device meets the safety specifications; such testing is normally conducted during the device's initial acceptance testing.

*Scheduled (Planned) Maintenance*—consists of some or all of the following activities: cleaning; decontamination; preventive maintenance; calibration; performance verification; and safety testing.

*Service*—consists of some or all of the following activities: installation; cleaning and/or decontamination; preventative maintenance; calibration; performance verification; safety testing; the repair of performance defects; repairs of safety defects; and cosmetic restoration. This does not include activities that would result in remanufacturing as that term is used in the FDA's Quality System/Good Manufacturing Practices regulation.

Two Device Condition codes were defined for use on the label:

*DC 1*—Device may have received cosmetic restoration but otherwise is in as is/unknown condition. Prior to use, device must be checked for proper performance and safety.

*DC 2*—Device is performing properly and safely and is ready for clinical use. If installation is required, the device must be checked again after installation. For devices labeled DC 2, users and purchasers should refer to the service documentation for additional information on the service(s) performed.

Another key element of the voluntary regulations included the establishment of a registry operated by a third party. The purpose of this third-party registry was to make hazard, recall, and safety related service notices available to all participants. Remarketers would have been obliged to make information on FDA and manufacturer hazard, recall, and safety related service notices available to their customers.